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ABSTRACT

Phase II of a study on the effectiveness of B. Feingold's recommended diet for hyperactive children involved the nine children (mean age 9 years) who had shown the "best" response to diet manipulation in Phase I. Each child served as his own control and was challenged with specified amounts of placebo and artificial color containing food items while being maintained on a strict elimination (Feingold) diet over an 11-week period. Parental and teacher ratings, classroom behavior observations, and neurological test scores obtained during baseline, placebo, and challenge conditions were not found to be adversely affected by the artificial color challenge materials. Comparable data gathered on a matched control group showed them to receive significantly better ratings than the hyperactive Ss on the majority of the comparison measures employed. Possible explanations for the discrepancy between the dramatic clinical-anecdotal reports that have been given and the more equivocal findings from formal experimental projects were considered. (Tables, graphs, and charts with statistical data are included.) (SBH)

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AN EXPERIMENTAL EVALUATION OF HYPERACTIVITY AND FOOD ADDITIVES[1]

1977 - PHASE II

J. Preston Harley, Ph.D., Charles G. Matthews, Ph.D.

and Peter L. Eichman, M. D.

EC110 479

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LIST OF ABBREVIATIONS

CNT - Control

EXP - Experimental

FDA - Food and Drug Administration

FSIQ - Full Scale Intelligence Quotient

ICGH - Interagency Collaborative Group on Hyperkinesis

IQ - Intelligence Quotient

K-P - Kaiser Permanente

mg - Milligrams

N - Number

NS - Not Significant

p - Probability Level

P-TQ - Parent-Teacher Questionaire

PIQ - Performance Intelligence Quotient

S - Subject

SD - Standard Deviation

t - Student t-Test

TQ - Test Quotient

VIQ - Verbal Intelligence Quotient

WISC - Wechsler Intelligence Scale for Children

WRAT - Wide Range Achievement Test

$\bar{X}$ - Arithmetic Mean

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J.P.H.
C.G.M.
P.L.E.

SUMMARY

Two complementary studies have been conducted at the University of Wisconsin following the research strategy guidelines specifically recommended by several scientific advisory groups to experimentally evaluate the Feingold hypothesis. The following is a summary of the first study.

In the Phase I study, 36 hyperactive boys age 6-12 and 10 hyperactive boys age 3-5 were studied. Food for the entire family was provided for the duration of the study. Half of the children (and their families) were first placed on a diet consisting of only those foods permitted by Dr. Feingold's diet and the other children were given menus which included ordinary amounts of artificial colors and flavors. After four weeks, the children were switched over to the other diet. The diets were comparable in appearance, taste and palatability. Neither the children nor their families or any members of the investigative team knew which diet a particular child was receiving at any point in the experiment. To assure objectivity, the children were assigned to their diet sequence by using a code which remained secret until the study was completed.

A large number of tests, examinations and behavioral observations were made throughout the study. Prior to beginning the diet phase of the study, each child was given neurological and psychological examinations, and hyperactivity ratings were obtained from parents and from the child's classroom teacher. Classroom observers carefully measured the frequency of restless, inattentive, disruptive and aggressive

behavior by the hyperactive child and made similar observations upon a "control" nonhyperactive classmate selected by the classroom teacher. The childrens' activity level was also measured in a standardized laboratory setting. The psychological tests, which included measures of attention, concentration, reaction time and motor coordination, and the laboratory observations were repeated at the end of each diet period. Parent and teacher ratings on degree of hyperactivity were made each week, and observations were made in the classroom twice per week throughout the study.

The overall results of the first study did not provide convincing support for the Feingold diet, certainly not in the larger group of 36 boys 6-12 years of age. The frequency with which favorable diet effects were judged to be present was highest in the subjective parent ratings, declined sharply in the teacher ratings, and essentially disappeared in the objective psychological classroom and observational data. It was also noted that the parental reports of improved behavior on the Feingold diet occurred only when the child was on the ordinary diet first followed by the Feingold diet, but <u>not</u> when the Feingold diet was given first and then followed by the control diet.

The smaller group of 10 preschool age boys showed a much stronger tendency to receive parental ratings which were in the direction of improved behavior when on the Feingold diet. Even though the parent ratings were not supported by improvement in psychological tests or in the laboratory grid room activity measurements, more detailed study of a larger group of preschool children was suggested by the Wisconsin team.

In the Phase II study reported in the present monograph, the 9 children who showed the "best" response to diet manipulation in the Phase I investigation, and who were available for study, were repeatedly challenged with specified amounts of placebo and artificial color containing food items while being maintained on a strict elimination (Feingold) diet over an eleven week period. Parental and teacher ratings, classroom behavior observations and neuropsychological test scores obtained during baseline, placebo and challenge conditions were not found to be adversely affected by the artificial color challenge materials. As expected, comparable data gathered on a matched control group showed them to receive significantly better ratings than the hyperactive subjects on the majority of the comparison measures employed. Possible explanations for the discrepancy between the dramatic clinical-anecdotal reports that have been given and the much more equivocal findings from formal experimental projects are presented.

SECTION I- Introduction[1]

1.1 Background

Based upon his clinical observations, Feingold (1975) has claimed that a significant percentage of hyperactive children benefit from a diet eliminating foods containing artificial flavors and colors and salicylates. The Interagency Collaborative Group on Hyperkinesis (ICGH) was formed by the Food and Drug Administration to review the evidence on the Feingold hypothesis and to present recommendations for future research (1976). The ICGH group in developing their recommendations for additional investigations of the Feingold hypothesis described several experimental designs. Under the heading called, "Model B Design" they noted the following:

> "In order to determine the general nutritional benefit of various diets, including the Feingold diet, it might be possible to develop an appropriately large sample of children with hyperkinetic syndrome and randomly assign them to either the K-P or another diet, judged by a group of nutrition experts to be nutritionally adequate. In order to equalize "placebo" effects, the control diet should involve the same degree of dietary difficulty for preparations as the K-P diet. This design might proceed as an independent group design (no crossover) or a counterbalanced crossover design in which the sequence of the diets was randomized."

Not entirely parenthetically, Model B is the model that was chosen and implemented for the Phase I study.

[1] A detailed presentation of hyperactivity in children and research pertaining to the Feingold hypothesis is given in our earlier monograph describing the first phase of our research (Harley, et al. 1977).

Under a heading called "Model Design C" the ICGH report states:

> The most direst test of the Feingold hypothesis is one in which the children who have responded to the diet be maintained on the same treatment regime plus the addition, in a double-blind fashion, of chocolate cookies, candy, or other food items prepared in such a fashion that one-half the items will contain no food additives and the other half will contain the eight more common food additives at levels calculated to average what a child on an ordinary diet might take-in daily."

The ICGH report then discussed the possibility of "combining aspects of Model Design B with Model Design C." Thus, one could start with a pool of carefully diagnosed hyperkinetic children who were randomly assigned to either the Feingold diet or a nutritionally adequate control diet (i.e., Model Design B). After an appropriate dietary trial of four weeks on each diet, using a crossover design, those children showing a favorable therapeutic response to the K-P diet but not to the control diet, would enter a Model Design C study, i.e., placebo versus challenge materials while being maintained on the Feingold diet, in a counterbalanced, double-blind crossover sequence.

The desirable combination of Models B and C recommended by the ICGH committee is in fact the Phase II research protocol proposed and now completed by the Wisconsin Group.

The purpose of the initial study (Phase I) of our research program was to ascertain the effectiveness, if any, of Feingold's recommended diet by comparing the behavior of hyperactive children under the K-P (Feingold) and control diet conditions. Forty-six hyperactive children were assigned to either the experimental, that is the K-P or Feingold diet, or the control diet following a two week baseline interval.

In brief, the results of our initial study indicate that, with the possible exception of a small preschool sample of children on whom

only limited data could be obtained, the overall results did not appear to offer strong support for the efficacy of the experimental or Feingold diet (Harley, et al., 1979). The frequency with which positive diet effects were judged to be present was highest in the subjective parental ratings, declined sharply in the teacher ratings, and essentially disappeared in the objective neuropsychological, classroom and laboratory observational data. The few significant findings related to diet that did emerge were viewed as requiring conservative interpretation for several reasons. First, given the very large number of statistical tests conducted, some of the differences obtained may be due to chance alone. Secondly, positive effects of the diet were primarily restricted to control diet first--experimental diet second; a diet order effect which has also been observed in an earlier investigation by Dr. Conners and his co-workers at the University of Pittsburgh (1976). Although no satisfactory explanation was readily apparent, the finding that the experimental diet seemed to "work" only when a control diet is given first served to attenuate the claimed efficacy of the experimental diet.

While there may well exist a subset of hyperactive children whose behavior is adversely affected by artificial food colors and flavors, the results of the initial study suggested that the subset is very small, and/or that the relationship of diet manipulations to behavioral change is much less dramatic and predictable than has been described in anecdotal-clinical reports.

The present Phase II of our research is concerned with those individual children who had shown the "best" response to diet man-

ipulation in Phase I. Each child served as his own control and was alternately challenged by food materials containing specified amounts of artificial food colors and by food materials without such synthetic food colorings.

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Interagency Collaborative Group on Hyperkinesis First report of the preliminary findings and recommendations. Submitted to the Assistant Secretary for Health, Education and Welfare, Washington, D.C., January, 1976.

SECTION II - Methodology

2.1 Subject Selection

Children selected for inclusion in the original study (Phase I) had to meet at least two of the following three criteria: First, a score of 15 or greater on the Conner's Parent-Teacher Questionnaire (P-TQ), indicating a moderate to severe degree of hyperactivity as rated by at least one parent; secondly, a score of 15 or greater rated by the child's teacher; and finally, if the child was given a score of less than 15 by either source, a primary diagnosis of hyperkinetic reaction by the child's physician was necessary. Children with a history of unequivocal neurological disease and/or significant brain damage, psychopathology, convulsive disorder or an IQ below 85 were rejected as project participants. Selection of subjects (Ss) for the present second stage of the experimentation was made by rank ordering the 46 Ss from the Phase I study on their behavioral ratings and classroom observations in terms of a favorable response to the K-P diet. The parent and teacher ratings, classroom behaviors, and laboratory observations were assigned equal weights in computing a diet response index for each subject. The 9 Ss selected for the study were those receiving the highest rank order and available for participation. In all instances, these Ss exceeded the 50th percentile of the total rank order in terms of a favorable response to the K-P diet. The mean ages for the hyperactive and control groups were 111 (SD=21) and 113 months (SD=21), respectively. None of the hyperactive Ss were receiving medication treatment for their behavior problem immediately prior to the study.

2.2 Procedure

Procedure for the study was as follows: After obtaining parental consent (Tables 2.0 and 2.1), each child was observed over four weeks of baseline; in the first two weeks social-psychological, classroom behavior, and dietary information was gathered, with the child and his family continuing on their regular diets. In the next two weeks of baseline, the entire family was placed on the K-P diet (Feingold, 1975) and this diet was strictly maintained throughout the study. All foods were provided for the entire family, and specially prepared treats were delivered to the school when the experimental child or any of his classmates had a birthday or wished to bring treats to school. After the 4 week baseline interval the nine experimental Ss were administered challenge and placebo material with multiple cross-overs during the experimental phase (9 weeks) of the project. The observer, parents, teachers, and project staff members did not know the placebo-challenge code. A week's supply of cookies or candy bars, two items per day, were labeled for each day of the week and were included in the weekly groceries for the family. Five of the Ss received the following sequence after baseline: placebo material for a two week period, followed by two weeks of challenge items, then another two weeks of placebo material, terminating with three weeks of challenge materials. The other experimental Ss received the opposite sequence after baseline: two weeks of challenge, concluding with three weeks of placebo.

2.3 Placebo-Challenge Materials

The placebo and chllenge food were in two forms: candy bars and

cookies. Each item contained a blend of half the "average" daily intake of 27 mg. of the certified food colors (Table 2.2). These figures were derived from national consumption data (Guidelines for Good Manufacturing Practice, 1968). The placebo items contained no synthetic food colors. Cookies and candy bars were alternately provided each week.

The placebo and challenge materials were developed under the aegis of the Nutrition Foundation. A group of eight experienced judges evaluated the placebo and challenge forms of the candy bars and cookies. Twenty-four separate judgments were made in each of the three separate evaluations of the unidentified products. Major attributes of the candy bars judged included: appearance, aroma, flavor, and texture. The cookies were rated on frosting appearance, cookie appearance, aroma, flavor and texture. The results of this testing conducted by the Quaker Research Laboratories indicated that the chocolate challenge cookies were not found to be significantly different from the placebo on any of the attribute scales measured by the panel. The challenge and placebo chocolate candy bars were found to be significantly different on several attributes; however, these findings were described as "fine differences perceived by a panel with repeated exposure to the candy bars" and more attributable to manufacturing procedures than to the food colors, per se. A non-expert adult taste panel was not able to distinguish any differences in the placebo versus challenge materials in either the cookie or candy bar materials (Quaker Laboratories, 1975). Post-experimental interviews revealed that none of the parents and/or children correctly identified the placebo versus challenge materials during the study.

2.4 Code

The specially prepared cookies and candy bars were labeled with four digit codes and designated for each particular S. A series of sealed envelopes, each containing the weekly code for each S, was kept in the Department of Neurology in order to have access to the code assignment if it became necessary to identify the type of materials being ingested by a S for medical or behavioral reasons. It was not necessary to secure the identity of the code for any S during the study. The sealed envelopes were presented to Mr. Ralph Hawley, Associate Dean of the University of Wisconsin Center for Health Sciences, who certified all the seals were intact prior to being opened at the conclusion of the study.

A supply of placebo materials was retained in the laboratory. Thus, if a child had a severe adverse reaction, his regularly scheduled materials (placebo or challenge) could be replaced with known placebos for the remainder of the week, in this way taking corrective steps but avoiding code disclosure. One child showing extreme behavioral disruption during the experimental phase of the project was placed on the known placebo cookie for one week, and at the parents' request his pre-experimental medications schedule was re-instituted for the final seven weeks of the study. Post-experimental breaking of the code revealed that this child had also been receiving the placebo cookie during the period of the disruptive behavior that prompted this "emergency" maneuver on the part of the experimenters. A second child had his medication schedule re-instituted at week 9 of the 13 week study and received known placebo materials during this final phase of the study. All subsequent data analyses were adjusted to reflect these procedural changes.

2.5 Dietary Compliance

Daily dietary records were maintained throughout the 11 week diet phase of the study by experimental S's parents to help assess maintenance of dietary compliance. The number of weekly dietary infractions for the individual experimental Ss maintained on the K-P diet are given in Table 2.3. Two Ss (1 and 4) had no reported dietary deviations. Subject 3 had the greatest number (6) of infractions. These data suggest that comparison of placebo and challenge periods is probably not seriously jeopardized by an unacceptable number of dietary infractions. "Technical" diet infractions occurred when a food not generally allowed on the K-P diet was consumed in the challenge phase. Each such instance is specified in Table 2.3.

2.6 Pre-post Experiment Height/Weight Changes

Table 2.4 presents individual Wechsler Intelligence Scale for Children Full Scale IQ, grade placement and pre and post Phase II height and weight data on the 9 experimental and the 9 control subjects. Inspection of the Table shows the close correspondence between control and experimental Ss on each of these measures, including amount of weight gained over the 13 weeks of the study by Ss on the elimination (Feingold) as opposed to a normal control diet. Detailed presentation and discussion of the nutritional aspects of the Feingold diet may be found in our Phase I monograph (Harley, et al., 1977).

2.7 Dependent Variables

The Conners' Parent-Teacher Questionnaire (P-TQ) was completed by S's mother, father, and teacher, independently on each Tuesday and Thursday for the 13 consecutive weeks (Table 2.5).

In addition to subjective parent and teacher ratings, behaviors in the classroom setting were recorded by trained observers. The experimental Ss and their matched, nonhyperactive controls, were observed each Tuesday and Thursday during the baseline and experimental periods, i.e., a total of 26 consecutive observations.

A battery of neuropsychological measures was administered on four separate occasions: at the end of the baseline (Week 4), at the end of first two week experimental periods (Weeks 6 and 8) and at the conclusion of the study (Week 13). The neuropsychologial dependent variables have been previously described in detail (Harley, et al., 1977).

Table 2.0 Special Consent to Participate in Research Study

University of Wisconsin
Center for Health Sciences

Name of Child_____ Age_____

Address_____ Date_____

1. This research project is a further investigation of the possible effects of food diets upon the behavior of hyperactive children in which you and your son participated last year. During the course of this current study once again your entire family will be requested to eat only those foods provided and/or designated by the research project. One diet will be utilized throughout the study. This diet will be exclusive of artificial food flavors and colors. In addition, all substances containing natural or synthetic salicylates will be eliminated. The diet will be tailored to your family's eating habits, and it will be balanced and nutritious. Specially prepared confections and/or baked goods will be supplied to your family. Some of these items will contain nine certified colors, blended in proportion to estimates based upon average daily U.S. consumption figures. The other items will not contain any artificial colors. These two types of food material will be given each day for the duration of the dietary period. Your son will be given a number of examinations and tests including: routine clinical laboratory studies (blood and urine analysis) and psychological tests of attention, memory, and concentration. You will be interviewed at the beginning of the project to obtain a current medical/social history and to determine the degree of activity of your child at the beginning of the study. A teacher rating scale for amount of "hyperactivity" in classroom will be completed daily. Parent ratings will also be gathered on a daily basis. We do hope that the information gained from the project will eventually prove useful to hyperactive children and their families. We will be happy to answer any questions that you may have concerning the project or the procedures to be employed. As you are well aware from your participation in the first stage of this project, the specially prepared food items containing the artificial colors may precipitate varying degrees of behavioral disruption. You are free to withdraw your consent and to discontinue participation at any time.

2. The procedures listed under Paragraph 1 have been explained to me by Dr._____ and I understand the nature and object of the procedures.

3. I hereby authorize Dr._____ and/or his associates or assistants of his choice to obtain the medical and behavioral information described in Paragraph 1 above.

_____ _____

Witness Signature of parent or guardian

Table 2.1 Authorization for Teacher Rating Scale Data

I hereby give permission to the classroom teacher(s) of my child _____ to complete the behavioral rating scales requested as part of a study being conducted at the University of Wisconsin Center for Health Sciences, Madison.

Signed _____
(parent or guardian)

Witness _____ Date _____

Table 2.2 Percentage of the Certified Colors Used in the Challenge Materials

COLOR	PERCENTAGE
Blue #1	3.12
Blue #2	1.70
Green #3	0.13
Red #3	6.08
Red #4	0.50
Red #40	38.28
Yellow #5	26.91
Yellow #6	22.74
Orange B	0.54
Total	100.00

Note: This certified color blend was developed under the direction of Dr. Samuel Zuckerman, Vice President of H. Kohnstamm and Company, Inc., New York, N.Y.

Table 2.3 Weekly Diet Infractions for Each Hyperactive Subject by Condition (Challenge and Placebo) for the Eleven Weeks on the K-P Diet Regime

	BASELINE		PLACEBO		CHALLENGE		PLACEBO		CHALLENGE			
	KP DIET ONLY		BARS	BARS	BARS	BARS	COOKIES	BARS	COOKIES	BARS	COOKIES	
S#	3	4	5	6	7	8	9	10	11	12	13	TOTAL
1	0	0	0	0	0	0	0	0	0	0	0	0
2	2	1	0	0	(2)	0	0	0	0	0	0	3
3	3	1	1	0	(1)	0	1	0	(1)	(1)	0	6
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	2	0	0	0	0	0	0	0	1	(1)	3

	BASELINE		CHALLENGE		PLACEBO		CHALLENGE		PLACEBO			
6	0	0	0	0	0	0	0	0	0	0	1	1
7	1	0	(1)	0	0	0	0	0	0	0	0	1
8	2	0	0	(1)	0	0	0	0	0	0	0	2
9	1	0	0	0	1	0	(1)	0	0	0	0	2
TOTAL	9	4	1	0	1	0	1	0	0	1	1	20

( ) = Technical Infraction Only; Occurring in Challenge Condition

Table 2.4 Pre-post Study Height and Weight Changes, Full Scale IQ and Grade Placement for the Individual Hyperactive and Control Subjects

Hyperactive Group

S#	FSIQ	GRADE	PRE HT (in.)	POST HT	PRE WT (lbs.)	POST WT
1	136	1	46.50	46.50	45.00	45.00
2	103	3	52.00	52.00	65.00	65.50
3	115	4	55.00	55.50	68.00	68.25
4	97	4	55.75	56.00	67.00	68.00
5	107	4	55.25	55.25	72.00	73.75
6	111	7	54.00	54.00	96.00	99.00
7	112	4	53.25	53.25	64.00	65.00
8	95	5	59.00	59.50	79.00	82.00
9	97	3	56.00	56.50	73.00	76.00
	$\bar{X}$ 108.11	$\bar{X}$ 3.88	$\bar{X}$ 54.10	$\bar{X}$ 54.22	$\bar{X}$ 69.89	$\bar{X}$ 71.39
	SD 12.72	SD 1.62	SD 3.45	SD 3.75	SD 13.55	SD 14.56

Control Group

101	121	1	45.00	45.00	46.00	47.00
102	105	3	52.50	52.50	70.00	70.00
103	117	4	52.50	52.50	64.50	66.00
104	119	4	53.75	53.75	61.50	63.00
105	107	4	54.25	54.25	66.00	64.25
106	96	4	53.00	53.50	68.25	69.50
107	99	7	56.00	56.00	71.50	73.75
108	123	4	57.25	57.25	68.00	69.00
109	101	5	63.00	63.00	97.50	101.00
	$\bar{X}$ 109.77	$\bar{X}$ 4.00	$\bar{X}$ 54.14	$\bar{X}$ 54.19	$\bar{X}$ 68.14	$\bar{X}$ 69.28
	SD 10.32	SD 1.50	SD 4.77	SD 4.78	SD 13.36	SD 14.14

Table 2.5 Conners Parent-Teacher Questionnaire (P-TQ)

	Not at All (0)	Just a Little (1)	Pretty Much (2)	Very Much (3)
1. Restless (overactive)	___	___	___	___
2. Excitable, impulsive	___	___	___	___
3. Disturbs other children	___	___	___	___
4. Fails to finish things he starts (short attention span)	___	___	___	___
5. Fidgeting	___	___	___	___
6. Inattentive, distractable	___	___	___	___
7. Demands must be met immediately; frustrated	___	___	___	___
8. Cries	___	___	___	___
9. Mood changes quickly	___	___	___	___
10. Temper outbursts (explosive and unpredicatble behavior)	___	___	___	___

SECTION II: REFERENCES

Descriptive sensory evaluation by experienced judges on candy bars and cookies with dye additives. Quaker Research Laboratories, Product Evaluation Report 3409-3 No. 2, April, 1975.

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Harley, J. P., Tomasi, L., Ray, R. S., Eichman, P. L., Matthews, C. G., Chun, R., Cleeland, C. S. and Traisman, E. An experimental evaluation of hyperactivity and food additives - Phase I. Monograph, Food Research Institute, University of Wisconsin-Madsion, 1977.

SECTION III - Classroom Observation Procedure[1]

3.1 Procedure

The behavior of the hyperactive children was recorded in the classroom situation using a procedure similar to the method described by Werry and Quay (1969). Observations were made during designated academic seat work. A control S was identified for each hyperactive S, matched on sex, grade and academic ability by the teacher. These children were selected as being "average" rather than "model or excellent" students. The identities of the hyperactive and control Ss were not revealed to the observers, the observers having been instructed only to observe "these two children". The observers were trained via video-tape classroom training sessions. A predetermined level of agreement was reached by all observers (75% agreement) prior to commencing the data collection. There were two reliability checks made on each observer during the course of the study.

The observer was positioned close enough to both children being observed to allow to clearly hear what was being said and to see what the children were doing at their desks. One child was observed for a twenty second interval. A ten second period followed for the recording of the appropriate symbols on the score sheet (Table 3.0). Behaviors occurring during this ten second period were not recorded. Thus, two observations were made per minute. The second child was observed for the next minute. There are 60 separate cells of observation, giving a total observing time of 30 minutes per child for each of the two weekly sessions.

[1]The procedure, methodology and training of personnel for classroom observations was directed by M. Cohen, Institute for Child Behavior and Development, University of Illinois-Champaign.

3.2 Definition of Behavioral Categories

3.21 (No) Deviant Behavior

Any behavior which contravenes any explicit or implicit rule by which the class or individual child operates. Therefore, it was necessary to determine the rules in a given classroom before undertaking any observations. The observer questioned the teacher about the conditions under which it is permissible for a child to leave his seat or to speak. A count was made of the number of observational units without the occurrence of a deviant behavior.

3.22 Gross Motor Activity

Any repetitive movements of the trunk, arms or legs including walking, running, hopping, skipping, jumping and rocking in seat. Also, such gross physical movements as arm flailing, bouncing in seat, leg swinging, and rocking and head swaying were included. Foot movements and hand movements alone were not counted.

3.23 Non-Work

Activity which the child engages in for self amusement, entertainment or stimulation. To be scored as non-work the activity must include, although not be limited to, the child's use of his hands to manipulate his own or community property so that such behavior is incompatible with learning. Examples: pencil play - rolling pencil on desk, waving, hitting on desk, marking with pencil, tearing paper, crumpling paper, hand movements near face, waving things near face, fiddling with clothes, scribbling on paper, patting body, daydreaming, staring, etc.

3.24 Disturbing Behavior

Any physical contact initiated or reciprocated by the child under observation with another person independent of the intent of the child (aggressive, affectional, or other). Physical contact made with another person by means of an object such as a book held in a hand or an object thrown, or some other disturbance of another person or child by the subject in which there is contact, not with the other's body but rather with objects about him such as his work, his desk, etc. Examples: grabbing objects or work, knocking objects off the other's desk, destroying other's property or pushing his desk. Vocalizations or other voluntary respiratory noises (e.g. such as whistling or grunting)which are not task related. Examples: calling the teacher without first raising hand, talking to others without permission, swearing, any noise which seems produced for the sake of noise.

3.25 Isolation

Scored if the child has been sent out of the room as a punishment or has been placed in a corner of the room. If the child is isolated in the classroom, other deviant behaviors which can be noted such as vocalizations and other noises are recorded.

3.26 On-Off Task Activity

This is a measure of the child's attention to designated task material. Attending was defined as the eyes being directed to the task material or to the teacher for a period of not less than 15 of the 20 second observation period. The child was considered on task when he can be clearly seen to be doing one task even though his eyes may be off his work, e.g., counting on his fingers, verbally working out math problems, etc. If a

child had his hand raised and was waiting for the teacher to come to him, he does not have to have his eyes on his work or on the teacher to be considered on task. Hand raising is considered on task behavior. A child was considered "off task" when he is engaged in some deviant behavior, as previously defined.

3.27 Teacher Contact

The teacher was defined as any person who was interacting with the children in the classroom rather than just observing them. Any contact between teacher and child whether initiated by child or by teacher was scored. These behaviors included such obvious contacts as talking to the child, but also less obvious ones such as gesturing or handing of materials to the child.

Contacts initiated by the child with the teacher, either positive or negative (talking back, refusing to work), were also scored.

Positive contacts included instructions and conversations with the individual child as well as with the class as a whole (during which the observed child would be expected to pay attention); presenting classroom material, announcements, praise or encouragement. Also, negative teacher contact or reprimanding behavior was recorded.

3.3 Scoring

The number of observations for each category was summed for the half hour scoring period and recorded separately for the two children in the classroom. The scores were coded to facilitate computer card preparation (Table 3.0). The Placebo-Challenge and Experimental-Control Code information was added after completion of the study.

3.4 Reliability

A ratio agreement (Werry and Quay, 1969) was calculated between each of the nine observers and the chief classroom observer on two separate occasions. The mean percent of agreement for the two reliability checks is given in Table 3.1 for the individual behavioral categories on the Deviant Behavior Frequency Record (Table 3.0) for the hyperactive group.

Table 3.0 Deviant Behavior Frequency Count Record

Child I _____ Date _____
(first name)

Child II _____ Observer _____
(first name)

1	I	- - -	- - -	11	I	- - -	- - -	21	I	- - -	- - -
2	II	- - -	- - -		II	- - -	- - -		II	- - -	- - -
3	I	- - -	- - -		I	- - -	- - -		I	- - -	- - -
4	II	- - -	- - -		II	- - -	- - -		II	- - -	- - -
5	I	- - -	- - -		I	- - -	- - -		I	- - -	- - -
6	II	- - -	- - -		II	- - -	- - -		II	- - -	- - -
7	I	- - -	- - -		I	- - -	- - -		I	- - -	- - -
8	II	- - -	- - -		II	- - -	- - -		II	- - -	- - -
9	I	- - -	- - -		I	- - -	- - -		I	- - -	- - -
10	II	- - -	- - -	20	II	- - -	- - -	30	II	- - -	- - -

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BEHAVIORAL CATEGORY		CHILD I Col.	CHILD II
___	No Dev.	1 - 2	1 - 2
M	Motor Act.	4 - 5	4 - 5
N	Nonwork	7 - 8	7 - 8
D	Disturbing	10 - 11	10 - 11
I	Isolation	13 - 14	13 - 14
___	On Task	16 - 17	16 - 17
//	Off Task	19 - 20	19 - 20
T		22 - 23	22 - 23
t		25 - 26	25 - 26
ℓ		28 - 29	28 - 29
T		31 - 32	31 - 32
Active=1 Placebo=2		61	61
S Exp=1 CNT=2		63	63
Week/Day Number		65 - 67	65 - 67
Check Yes=1		69	69
Observer		71 - 72	71 - 72
Day Code		74 - 76	74 - 76
Subject Number		78 - 80	78 - 80

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Table 3.1 Mean Percent of Ratio Agreement for the Classroom Observers for Two Separate Reliability Checks for the Hyperactive Group.

Behavioral Category	Check #1	Check #2
No Deviant Behavior	94	92
Gross Motor Activity	79	77
Non-Work	65	70
Disturbing Behavior	87	75
Isolation	*	*
On-Task	94	93
Off-Task	75	80
Teacher Initiated - Positive	88	80
Child Initiated - Positive	79	60
Child Initiated - Negative	62	100
Teacher Initiated - Negative	83	*

*Behavior did not occur during the observation period.

SECTION III: REFERENCES

Werry, J. S. and Quay, H. C. Observing the classroom behavior of elementary school children. Exceptional Children, 1969, 35, 451-469.

SECTION IV - RESULTS

4.1 Conners P-TQ

4.11 Phase I Study

Parent and teacher P-TQ ratings of the nine hyperactive Ss made during the experimental (additive free) and control diet conditions in the Phase I study are presented in Table 4.0. A significant diminution of "hyperactive" behavior was observed by both the mother (t=5.37, df=8, p <.001) and father (t=10.84, df=8, p <.001) when these children were maintained on the experimental diet in comparison to the control diet. The improved behavior on the experimental diet indicated by teachers in the classroom failed to reach statistical significance (t=2.11, df=8, NS). These data are graphically depicted in Figure 4.0.

4.12 Baseline-Hyperactive versus Control Groups

The mean behavioral ratings made during the first two weeks of baseline on the hyperactive and control groups (during which time the families of the hyperactive children continued on their regular diet regimen) were compared. Table 4.1 shows that the mothers (t=5.67, df=16, p <.001), fathers (t=5.95, df=14, p <.001) and teachers (t=3.27, df=16, p <.01) of the hyperactive Ss rated the children as significantly more "hyperactive" than the control group. Similar results were found when the mean P-TQ ratings made by the parents and teachers were compared (Table 4.2) for the hyperactive and control groups for the last two weeks of baseline. During these last two weeks of baseline, families of the hyperactive

Ss were provided with all food needed for the strict maintenance of the elimination diet.

The hyperactive group demonstrated an improvement in behavior (Table 4.3) as judged by the mothers from the first ($\bar{x}$=15.06) to the last ($\bar{x}$=11.42) weeks of baseline (t=2.94, df=8, p <.02). No significant alterations in P-TQ ratings were shown in the evaluations made by the fathers (t=1.43, df=7, NS) or teachers (t=1.08, df=8, NS).

4.13 Hyperactive Subjects-Challenge versus Placebo Conditions

The mean P-TQ ratings of the hyperactive Ss under the combined placebo conditions were not found to be different from those obtained in the challenge periods (Table 4.4) made by the mothers (t<1, NS), fathers (t<1, NS) or teachers (t<1, NS).

The mean P-TQ for the observations made during all of the placebo periods for the hyperactive Ss were compared to the control group (Table 4.5). The behavior of the hyperactive group was judged to be significantly more disruptive than the control group for the corresponding time periods by the mother (t=4.18, df=16, p <.001), father (t=5.01, df=14, p <.001) and teacher (t=3.20, df=16, p <.01). Similarly, the P-TQ ratings made by the mothers (t=7.83, df=15, p <.001), fathers (t=5.47, df=14, p <.001) and teachers (t=3.33, df=15, p <.01) for the combined challenge periods indicated presence of more severe "hyperactive" behaviors in the hyperactive than control Ss (Table 4.6).

The mean P-TQ ratings for Ss 1-5 (receiving the Placebo-Challenge-Placebo-Challenge Sequence) for mother, father, and teacher are shown

in Figure 4.1. Inspection of Figure 4.1 does not reveal striking challenge effect, and the ratings which seem most in accord with the hypothesis are in large part supplied by the mothers. Inspection of Figure 4.2 is even less suggestive of any marked or consistent challenge versus placebo effect upon behavioral ratings for subjects 5-9 who received the opposite experimental sequence.

Figure 4.3 shows the consistently low rating given the 9 non-hyperactive, control children by mothers, fathers, and teachers over the 13 weeks of the experiment; their average rating being one-third or less than that of the hyperactive sample. This difference between the hyperactive and control subjects demonstrates the sensitivity of the Conners P-TQ rating scale to the behaviors under study.

4.2 Classroom Behavior

4.21 Baseline-Hyperactive versus Control Groups

In addition to separate analysis of the individual behavioral categories, the gross motor activity, non-work, disturbing behavior and off-task rating classifications were combined to yield a single composite disruptive behavior index. The large variability in teaching styles and classrooms precluded meaningful analysis of the teacher-subject interaction data.

In the first weeks of baseline the hyperactive group demonstrated more non-work (t=3.27, df=16, p <.05) than the control group in the classroom (Table 4.7). The control Ss have more periods of no deviant (t=2.69, df=16, p <.05) and on-task (t=2.09, df=16, p <.06) behavior than the hyperactive group of children. These between-group

differences were also obtained in the last two weeks of baseline (Table 4.8). In addition, the hyperactive Ss were also found to be significantly different from the control group ($t=2.43$, $df=16$, $p < .05$) on the composite disruptive behavior index. Table 4.9 shows that behavior of the hyperactive Ss remained relatively unchanged during the first and last two weeks of baseline as measured by the classroom observers.

4.22 Hyperactive Subjects-Challenge versus Placebo Conditions

The hyperactive Ss did not demonstrate significant differences between the placebo and challenge conditions for any of the classroom behaviors measured (Table 4.10). Although the control group consistently demonstrated fewer "hyperactive" behaviors than the hyperactive group during the placebo (Table 4.11) and challenge (Table 4.12) conditions in the classroom setting, intrasubject variability was so great that statistically significant differences were restricted to the "non-work" rating dimension.

Graphic comparisons of the no deviant, motor activity, non-work, disturbing, on-task, off-task, and composite disruptive behavior index are presented in Figures 4.4-4.10, respectively for the hyperactive and control groups.

4.3 Neuropsychological Measures

4.31 Baseline-Hyperactive versus Control Groups

No statistically significant differences were obtained between the hyperactive and control groups for the neuropsychological measurements taken at baseline (Table 4.13). The control Ss did, however, display better scores on the Continuous Performance Test (CPT), a measure of attention/concentration (Table 4.14).

4.32 Hyperactive Subjects-Baseline versus Placebo and Challenge Conditions

The neuropsychological performances of the hyperactive Ss obtained at the baseline examination were compared with the placebo and challenge testings separately (Table 4.15). None of these statistical comparisons were significant. When the performances in the challenge and placebo treatments were analyzed the single significant result was for the Coding subtest of the Wechsler Intelligence Scale for Children. Better scores were obtained by the hyperactive Ss in the placebo as compared to the challenge phase, $t=4.23$, $df=8$, $p < .01$. Scores on the CPT were not different between the challenge and placebo treatments in the hyperactive group (Table 4.16).

Table 4.0 Comparison of the Mean Conners P-TQ Ratings by Mother, Father and Teacher for the Experimental (K-P) and Control Diet Conditions Made in the Phase I Experiment for the Nine Hyperactive Children Selected for Participation in the Challenge Study

RATER	DIET CONDITION EXPERIMENTAL VS CONTROL			t	p
MOTHER	$\bar{X}$	12.21	19.28	5.37	<.001
	SD	5.57	4.93		
FATHER	$\bar{X}$	11.27	18.29	10.84	<.001
	SD	4.83	3.46		
TEACHER	$\bar{X}$	12.06	15.47	2.11	NS
	SD	5.69	5.75		

Table 4.1 Comparison of the Hyperactive and Control Groups for the Mean Conners P-TQ Ratings by the Mother, Father and Teacher during the First Two Weeks of Baseline (Regular Diet)

RATER		SUBJECTS HYPERACTIVE	VS CONTROL	t	p
MOTHER	$\bar{X}$	15.06	4.34	5.67	<.001
	SD	5.21	2.23		
FATHER	$\bar{X}$	14.31	3.59	5.95	<.001
	SD	4.40	2.57		
TEACHER	$\bar{X}$	12.31	3.42	3.27	<.01
	SD	7.24	3.78		

Table 4.2 Comparison of the Hyperactive and Control Groups for the Mean Conners P-TQ Ratings by the Mother, Father and Teacher during the Last Two Weeks of Baseline (K-P Diet)

RATER		SUBJECTS HYPERACTIVE	VS CONTROL	t	p
MOTHER	$\bar{X}$	11.42	3.75	3.59	<.01
	SD	5.55	3.19		
FATHER	$\bar{X}$	13.00	3.56	5.08	<.001
	SD	4.19	3.17		
TEACHER	$\bar{X}$	11.14	2.56	4.12	<.001
	SD	5.90	2.05		

Table 4.3 Comparison of the Mean Conners P-TQ Ratings by Mother, Father and Teacher during the First Two Weeks of Baseline (Regular Diet) and the Last Two Weeks of Baseline (K-P Diet) for the Hyperactive Subjects

RATER		BASELINE I VS BASELINE II		t	p
MOTHER	$\bar{X}$	15.06	11.42	2.94	<.02
	SD	5.21	5.55		
FATHER	$\bar{X}$	14.31	13.00	1.43	NS
	SD	4.40	4.19		
TEACHER	$\bar{X}$	12.31	11.14	1.08	NS
	SD	7.24	5.90		

Table 4.4 Comparison of the Mean Conners P-TQ Ratings by Mother, Father and Teacher for the Challenge and Placebo Conditions for the Hyperactive Subjects

RATER		CONDITION PLACEBO	CONDITION VS CHALLENGE	t	p
MOTHER	$\bar{X}$	12.86	14.50	.728	NS
	SD	6.39	3.10		
FATHER	$\bar{X}$	12.04	12.14	.436	NS
	SD	4.70	3.35		
TEACHER	$\bar{X}$	8.86	9.08	.315	NS
	SD	6.52	5.52		

Table 4.5 Mean Conners P-TQ Ratings by Mother, Father and Teacher for the Hyperactive Versus Control Subjects for the Placebo Periods

RATER		SUBJECTS HYPERACTIVE	VS CONTROL	t	p
MOTHER	$\bar{X}$	13.94	3.74	4.18	<.001
	SD	6.27	3.12		
FATHER	$\bar{X}$	12.37	3.48	5.01	<.001
	SD	4.36	2.49		
TEACHER	$\bar{X}$	9.88	2.46	3.20	<.01
	SD	6.79	1.51		

Table 4.6 Mean Conners P-TQ Ratings by Mother, Father and Teacher for the Hyperactive Versus Control Subjects for the Challenge Periods

RATER		SUBJECTS HYPERACTIVE	VS CONTROL	t	p
MOTHER	$\bar{X}$	14.35	3.43	7.83	<.001
	SD	3.09	2.60		
FATHER	$\bar{X}$	11.93	3.26	5.47	<.001
	SD	3.64	2.62		
TEACHER	$\bar{X}$	9.28	2.53	3.33	<.01
	SD	5.51	1.72		

Table 4.7 Comparison of the Mean Frequency of Classroom Behaviors for the Hyperactive and Control Groups during the First Two Weeks of Baseline (Regular Diet).

CLASSROOM BEHAVIORS		SUBJECTS HYPERACTIVE VS CONTROL		t	p
NO DEVIANT	$\bar{x}$	14.11	19.44	2.69	<.05
	SD	4.53	3.87		
MOTOR	$\bar{x}$	7.82	5.81	1.29	NS
	SD	2.73	3.86		
NON-WORK	$\bar{x}$	7.25	3.64	3.27	<.05
	SD	2.86	1.68		
DISTURBING	$\bar{x}$	5.39	4.19	.91	NS
	SD	3.33	2.07		
ON-TASK	$\bar{x}$	18.92	22.94	2.09	<.06
	SD	4.79	3.27		
OFF-TASK	$\bar{x}$	10.00	7.72	1.08	NS
	SD	5.21	3.60		
DISRUPTIVE INDEX	$\bar{x}$	29.89	21.61	1.73	NS
	SD	10.90	9.36		

Table 4.8 Comparison of the Mean Frequency of Classroom Behaviors for the Hyperactive and Control Groups during the Last Two Weeks of Baseline (K-P Diet).

CLASSROOM BEHAVIOR		SUBJECTS HYPERACTIVE VS	CONTROL	t	p
NO DEVIANT	$\bar{x}$	14.19	20.25	2.51	<.05
	SD	6.12	3.87		
MOTOR	$\bar{x}$	8.97	5.89	1.74	NS
	SD	4.47	2.85		
NON-WORK	$\bar{x}$	7.19	3.03	2.95	<.01
	SD	4.04	1.26		
DISTURBING	$\bar{x}$	6.83	4.11	1.08	NS
	SD	6.64	3.57		
ON-TASK	$\bar{x}$	19.22	24.19	2.16	<.05
	SD	5.83	3.65		
OFF-TASK	$\bar{x}$	10.25	5.72	2.04	NS
	SD	5.74	3.37		
DISRUPTIVE INDEX	$\bar{x}$	34.00	18.69	2.43	<.05
	SD	16.70	8.70		

Table 4.9 Comparison of the Mean Frequency of Classroom Behaviors for the Hyperactive Subjects during the First and Last Two Weeks of Baseline.

CLASSROOM BEHAVIOR		CONDITON: BASELINE I	BASELINE II	t	p
NO DEVIANT	$\bar{x}$	14.11	14.19	.06	NS
	SD	4.53	6.12		
MOTOR	$\bar{x}$	7.82	8.97	.86	NS
	SD	2.73	4.47		
NON-WORK	$\bar{x}$	7.25	7.19	.06	NS
	SD	2.86	4.04		
DISTURBING	$\bar{x}$	5.39	6.83	.93	NS
	SD	3.33	6.64		
ON-TASK	$\bar{x}$	18.92	19.23	.26	NS
	SD	4.79	5.85		
OFF-TASK	$\bar{x}$	10.00	10.25	.18	NS
	SD	5.21	5.74		
DISRUPTIVE INDEX	$\bar{x}$	29.89	34.00	1.08	NS
	SD	10.90	16.70		

Table 4.10 Comparison of the Mean Frequency of Classroom Behaviors For the Hyperactive group during the Placebo and Challenge Treatments.

CLASSROOM BEHAVIOR		CONDITION PLACEBO	VS CHALLENGE	t	p
NO DEVIANT	$\bar{x}$	15.90	16.25	.29	NS
	SD	6.85	7.25		
MOTOR	$\bar{x}$	7.87	7.27	.84	NS
	SD	5.98	4.96		
NON-WORK	$\bar{x}$	5.98	5.31	.88	NS
	SD	3.91	3.00		
DISTURBING	$\bar{x}$	6.18	5.93	.40	NS
	SD	5.06	6.51		
ON-TASK	$\bar{x}$	21.17	20.14	.916	NS
	SD	5.48	6.46		
OFF-TASK	$\bar{x}$	8.69	9.59	.77	NS
	SD	5.33	6.39		
DISRUPTIVE INDEX	$\bar{x}$	28.36	27.27	.49	NS
	SD	18.40	19.50		

Table 4.11 Comparison of the Mean Frequency of Classroom Behaviors for the Hyperactive versus Control Subjects for the Placebo Periods.

BEHAVIORAL CATEGORY		GROUP HYPERACTIVE	VS CONTROL	t	p
NO DEVIANT	$\bar{x}$	15.96	20.12	1.61	NS
	SD	6.41	4.37		
MOTOR	$\bar{x}$	7.69	6.06	.71	NS
	SD	5.62	4.08		
NON-WORK	$\bar{x}$	5.73	2.12	2.77	<.02
	SD	3.73	1.18		
DISTURBING	$\bar{x}$	5.69	4.01	.86	NS
	SD	4.96	3.13		
ON-TASK	$\bar{x}$	21.29	24.48	1.65	NS
	SD	5.14	2.73		
OFF-TASK	$\bar{x}$	8.59	5.36	1.72	NS
	SD	5.00	2.62		
DISRUPTIVE INDEX	$\bar{x}$	27.57	17.53	1.59	NS
	SD	17.40	7.51		

Table 4.12 Comparison of the Mean Frequency of Classroom Behaviors for the Hyperactive versus Control Subjects for the Challenge Periods.

BEHAVIORAL CATEGORY		GROUP HYPERACTIVE VS CONTROL		t	p
NO DEVIANT	$\bar{x}$	16.25	20.36	1.44	NS
	SD	7.25	3.74		
MOTOR	$\bar{x}$	7.27	5.00	1.12	NS
	SD	4.96	3.01		
NON-WORK	$\bar{x}$	5.31	2.80	2.27	<.06
	SD	3.00	0.95		
DISTURBING	$\bar{x}$	5.93	4.06	.74	NS
	SD	6.51	3.12		
ON-TASK	$\bar{x}$	20.14	24.10	1.60	NS
	SD	6.46	2.85		
OFF-TASK	$\bar{x}$	9.73	6.26	1.48	NS
	SD	6.19	2.56		
DISRUPTIVE INDEX	$\bar{x}$	27.27	17.92	1.27	NS
	SD	19.50	7.77		

Table 4.13 Comparison of Neuropsychological Measures for the Hyperactive and Control Subjects at Baseline

NEUROPSYCHOLOGICAL VARIABLES		SUBJECTS HYPERACTIVE	VS CONTROL	t	p
WISC					
VIQ	$\bar{X}$	105.22	104.78	.08	NS
	SD	12.80	9.35		
PIQ	$\bar{X}$	109.44	113.00	.63	NS
	SD	11.80	12.20		
FSIQ	$\bar{X}$	108.11	109.78	.31	NS
	SD	12.70	10.30		
Digit Span	$\bar{X}$	10.67	9.89	.48	NS
	SD	4.24	2.32		
Coding	$\bar{X}$	11.56	12.22	.50	NS
	SD	3.09	2.59		
WRAT					
Reading	$\bar{X}$	4.46	4.90	.53	NS
	SD	1.73	1.86		
Spelling	$\bar{X}$	3.51	4.16	.97	NS
	SD	1.12	1.65		
Arithmetic	$\bar{X}$	3.56	3.86	.58	NS
	SD	1.13	1.05		
FINGER TAPPING					
Dominant Hand	$\bar{X}$	33.44	32.22	.44	NS
	SD	6.19	5.70		
Nondominant Hand	$\bar{X}$	29.44	30.89	.54	NS
	SD	5.22	6.19		
KNOX	$\bar{X}$	10.22	11.56	1.83	NS
	SD	1.94	1.01		
PORTEUS MAZE					
Qualitative Score	$\bar{X}$	34.78	34.78	.00	NS
	SD	30.00	23.10		
TQ	$\bar{X}$	128.56	125.11	1.00	NS
	SD	7.42	7.24		

Table 4.14 Continuous Performance Test Scores for Hyperactive and Control School-Age Subjects at Baseline

		X-SERIES				AX-SERIES			
		ABS[1]	REL[2]	ERR[3]	OMIT[4]	ABS	REL	ERR	OMIT
HYPERACTIVE	$\bar{X}$	93.02[a]	81.13	19.11	4.89[b]	85.92[c]	76.25	20.72	15.00[d]
GROUP	SD	6.40	19.60	21.70	4.48	11.30	16.90	15.90	8.58
CONTROL	$\bar{X}$	97.94	92.17	6.22	1.44	95.63	85.73	12.61	3.22
GROUP	SD	2.58	6.86	5.95	1.81	3.84	11.70	12.50	2.73

[1]ABS = (Correct Responses/Number of Significant Stimuli) x 100

[2]REL = (Correct Responses/Total Responses) x 100

[3]ERR = Responses to Nonsignificant Stimuli

[4]OMIT = Failure to Respond to Significant Stimuli

Hyperactive versus Control Group Comparisons

[a] $t=2.14$, $df=16$, $p < .06$

[b] $t=2.14$, $df=16$, $p < .06$

[c] $t=2.44$, $df=16$, $p < .04$

[d] $t=3.92$, $df=16$, $p < .004$

Table 4.15 Means and Standard Deviations of the Neuropsychological Measures made during the Baseline, Placebo and Challenge Conditions for the Hyperactive Subjects.

NEUROPSYCHOLOGICAL VARIABLES	TREATMENT CONDITION					
	BASELINE		PLACEBO		CHALLENGE	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
WISC[1]						
Digit Span	10.67	4.24	9.25	3.60	9.94	2.43
Coding	11.56	3.09	13.44[a]	3.21	11.61[a]	3.09
WRAT[2]						
Arithmetic	3.56	1.13	3.44	.82	3.43	.75
KNOX CUBES[3]	10.22	1.94	9.86	3.05	9.25	3.01
PORTEUS MAZE[4]	128.56	7.42	127.06	6.22	127.39	9.77
FINGER TAPPING[5]						
Dominant Hand	29.44	11.10	29.78	11.10	32.94	6.26
Nondominant Hand	29.44	5.22	29.89	2.99	30.78	4.94
STATIC STEADINESS[6]						
Dominant Hand	40.56	27.70	48.50	34.90	48.94	26.50
Nondominant Hand	51.78	33.30	55.56	32.30	62.39	26.40
PEGBOARD[7]						
Dominant Hand	63.67	20.50	68.56	16.30	69.22	15.80
Nondominant Hand	84.56	18.90	76.89	15.50	74.56	17.60
CONTINUOUS PERFORMANCE TEST[8]						
X-Series	81.13	19.60	82.04	24.20	86.05	19.80
AX-Series	76.25	16.90	76.49	18.20	71.96	18.10

[a]Placebo versus challenge condition, t=4.23, df=8, p <.01.

Table 4.15 (Cont'd.)

[1]Age corrected standard scores on digit recall and visual motor learning tasks

[2]Grade placement equivalency score

[3]Raw score mean of two trials - immediate visual memory span task

[4]Age corrected score (Test Quotient) - planning, foresight, motor control task

[5]Number of taps in 10 seconds

[6]Contact time (sec.) on stylus-maze tracing and hand tremor tasks

[7]Time to complete (sec.) fine finger dexterity task

[8]Relative score - number of correct responses/total number of responses x 100 - visual attention task

Table 4.16 Continuous Performance Test Scores for Hyperactive Subjects for the Placebo and Challenge Conditions

		X-SERIES				AX-SERIES			
		ABS[1]	REL[2]	EER[3]	OMIT[4]	ABS	REL	ERR	OMIT
PLACEBO	$\bar{x}$	86.98	82.04	14.61	8.44	82.70	76.49	21.56	12.11
	SD	21.4	24.2	20.4	12.6	15.5	18.2	20.8	10.9
CHALLENGE	$\bar{x}$	85.00	86.05	9.72	7.11	76.79	71.96	21.28	18.75
	SD	19.9	19.8	13.5	7.71	20.9	18.10	11.3	13.9

[1]ABS = (Correct Responses/Number of Significant Stimuli) x 100

[2]REL = (Correct Responses/Total Responses) x 100

[3]ERR = Responses to Nonsignificant Stimuli

[4]OMIT = Failure to Respond to Significant Stimuli

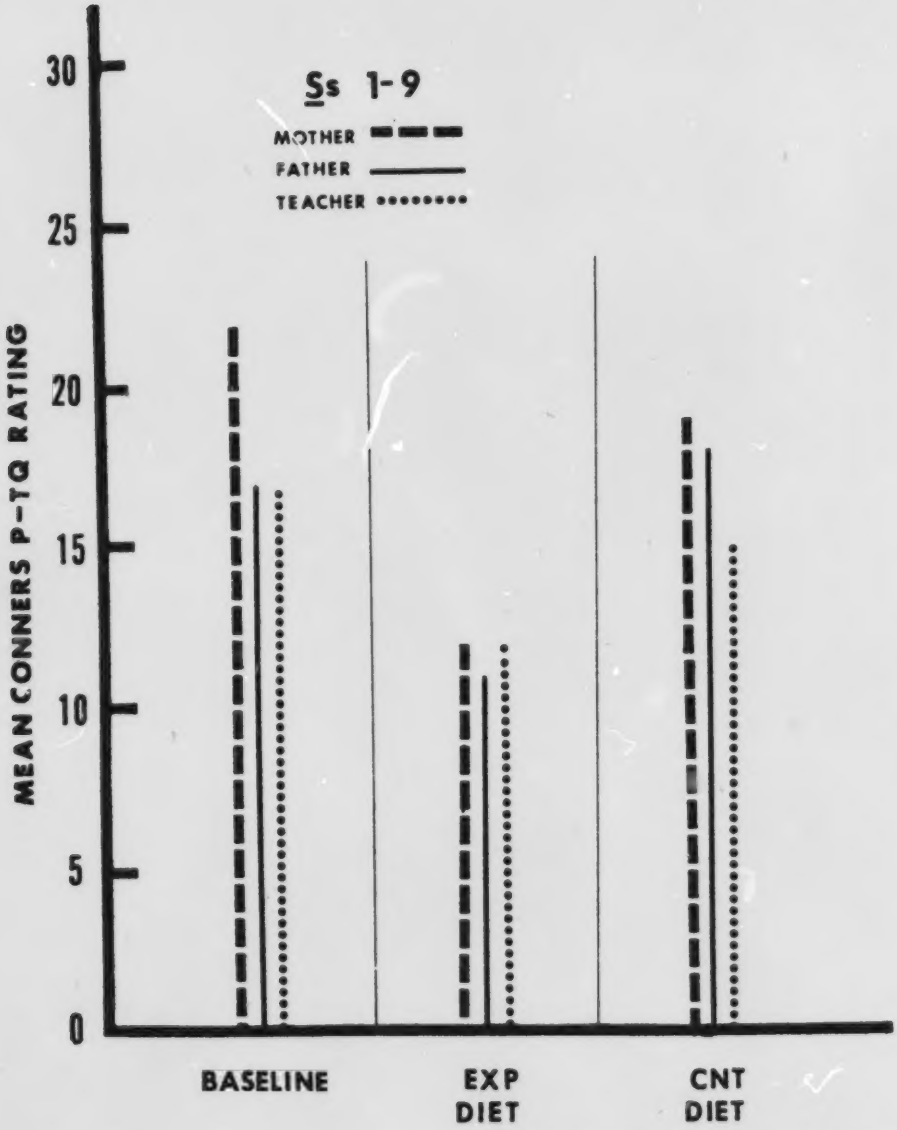

Figure 4.0 Mean Conners P-TQ Ratings Obtained in the Phase I Study for the Nine Hyperactive Subjects Selected for the Phase II Experiment

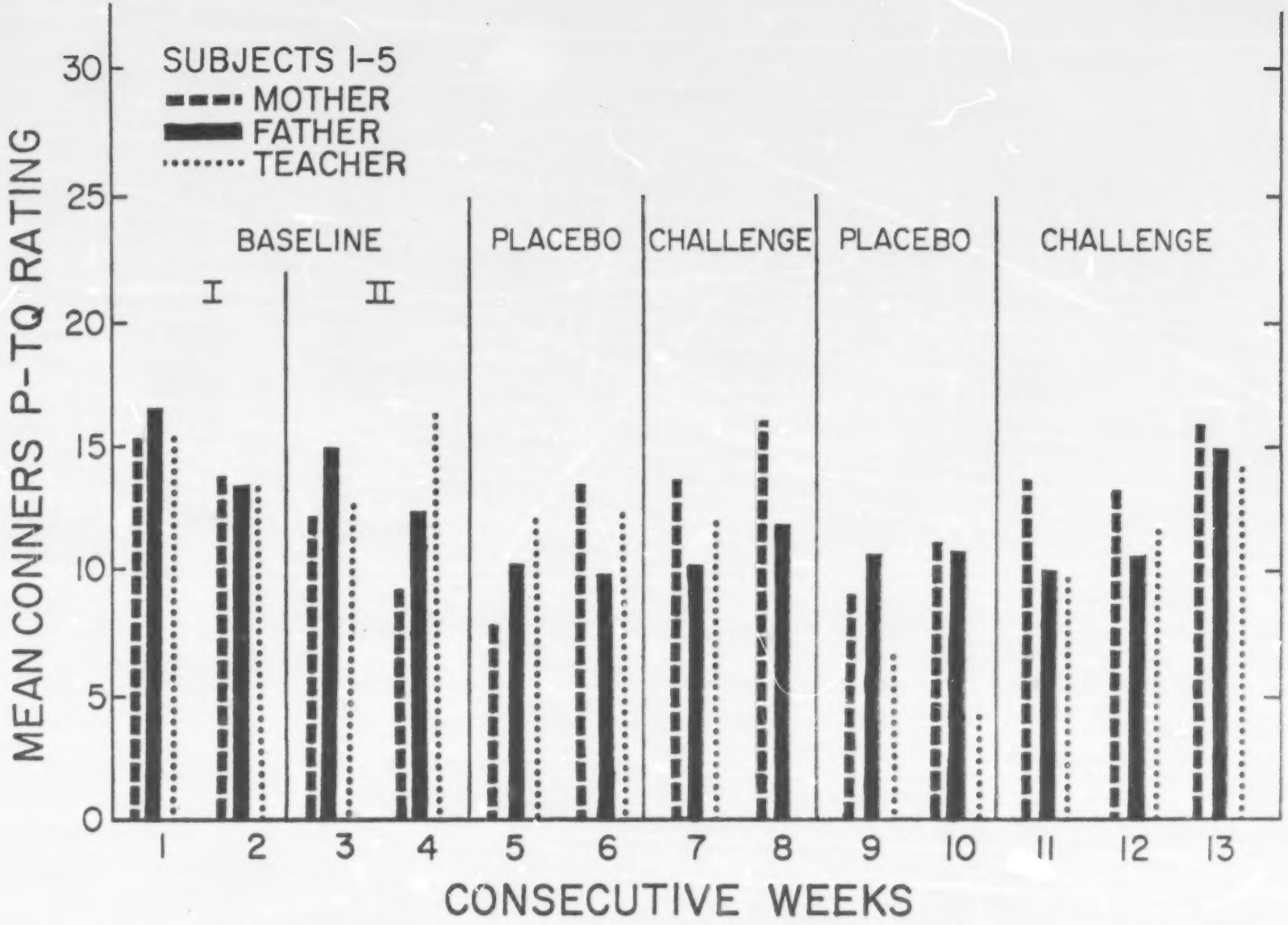

Figure 4.1 Weekly Mean Conners P-TQ Ratings for the Five Subjects Receiving the Placebo-Challenge-Placebo-Challenge Sequence

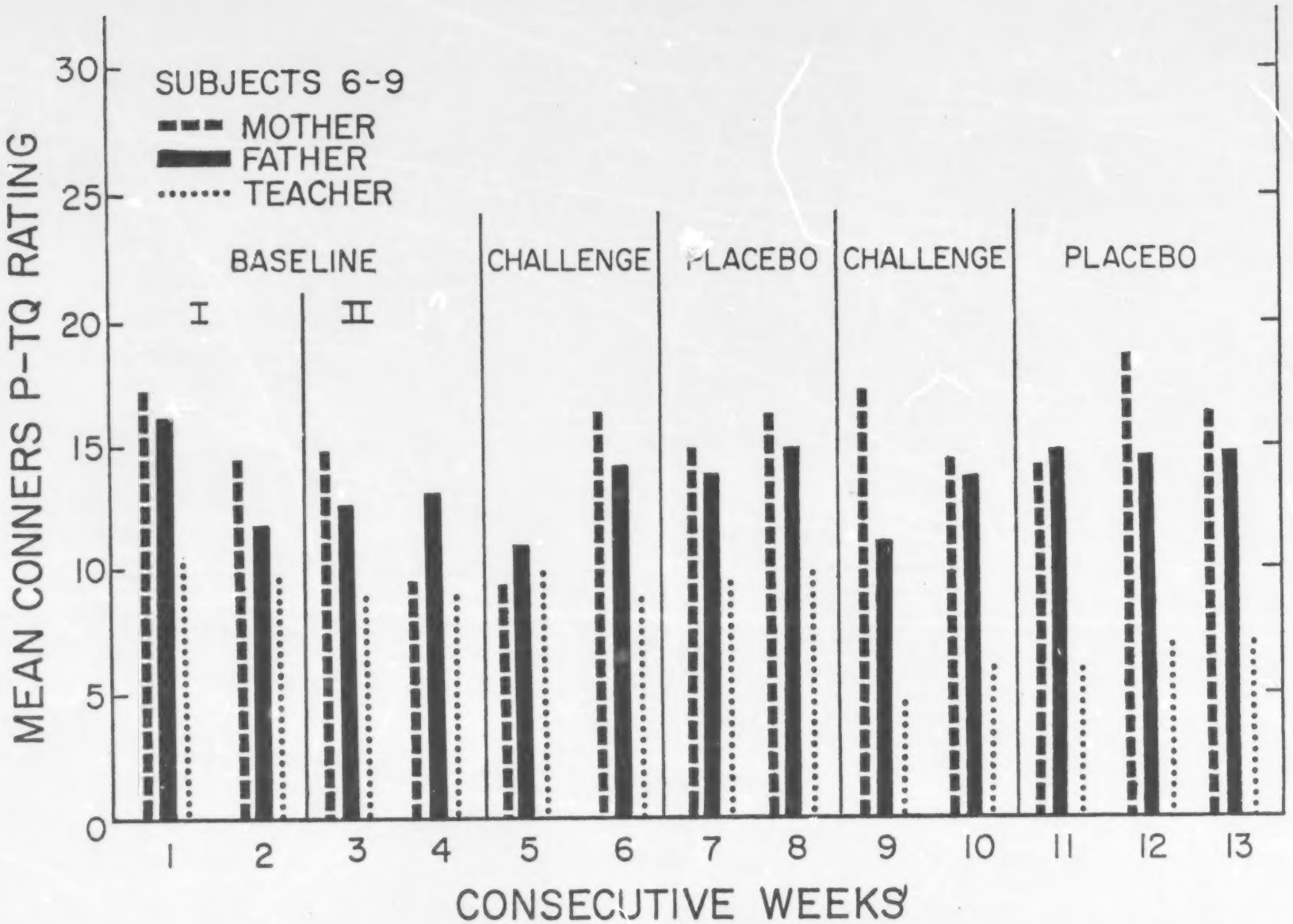

Figure 4.2 Weekly Mean Conners P-TQ Ratings for the Four Subjects Receiving the Challenge-Placebo-Challenge-Placebo Sequence

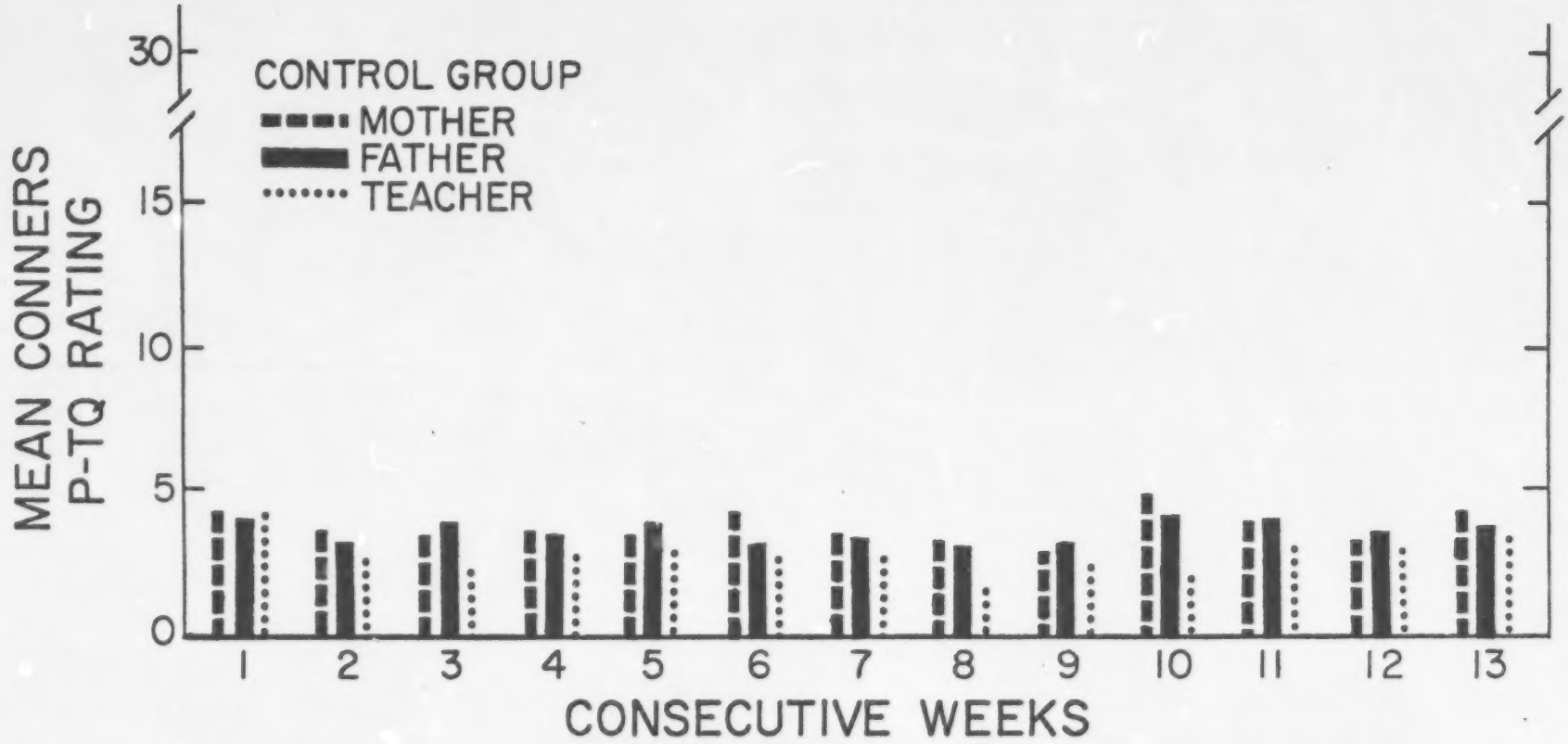

Figure 4.3 Weekly Mean Conners P-TQ Ratings for the Nine Control Subjects

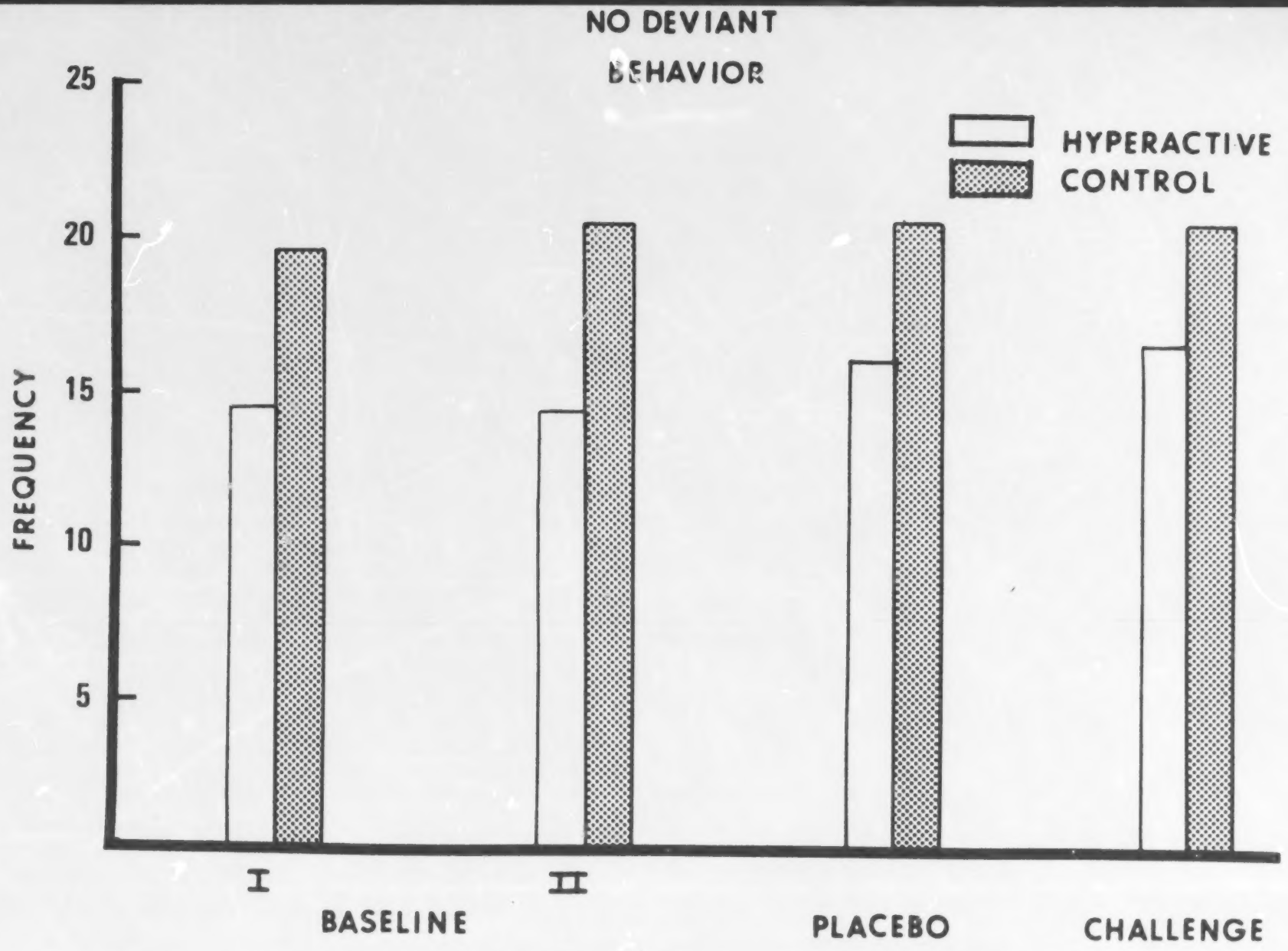

Figure 4.4 Mean No Deviant Classroom Behavior for the Hyperactive and Control Groups in Each Condition

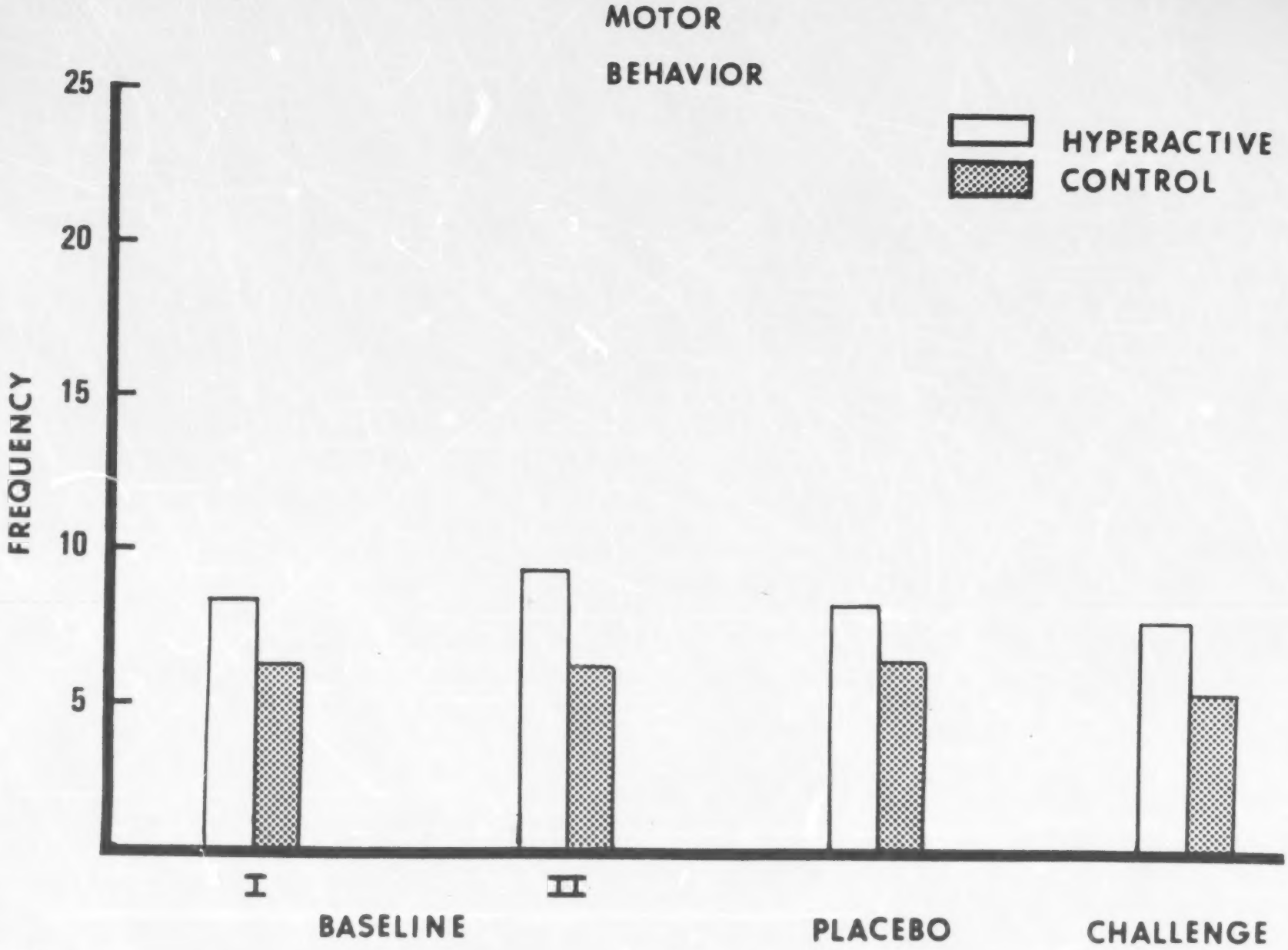

Figure 4.5 Mean Motor Classroom Behavior for the Hyperactive and Control Groups in Each Condition

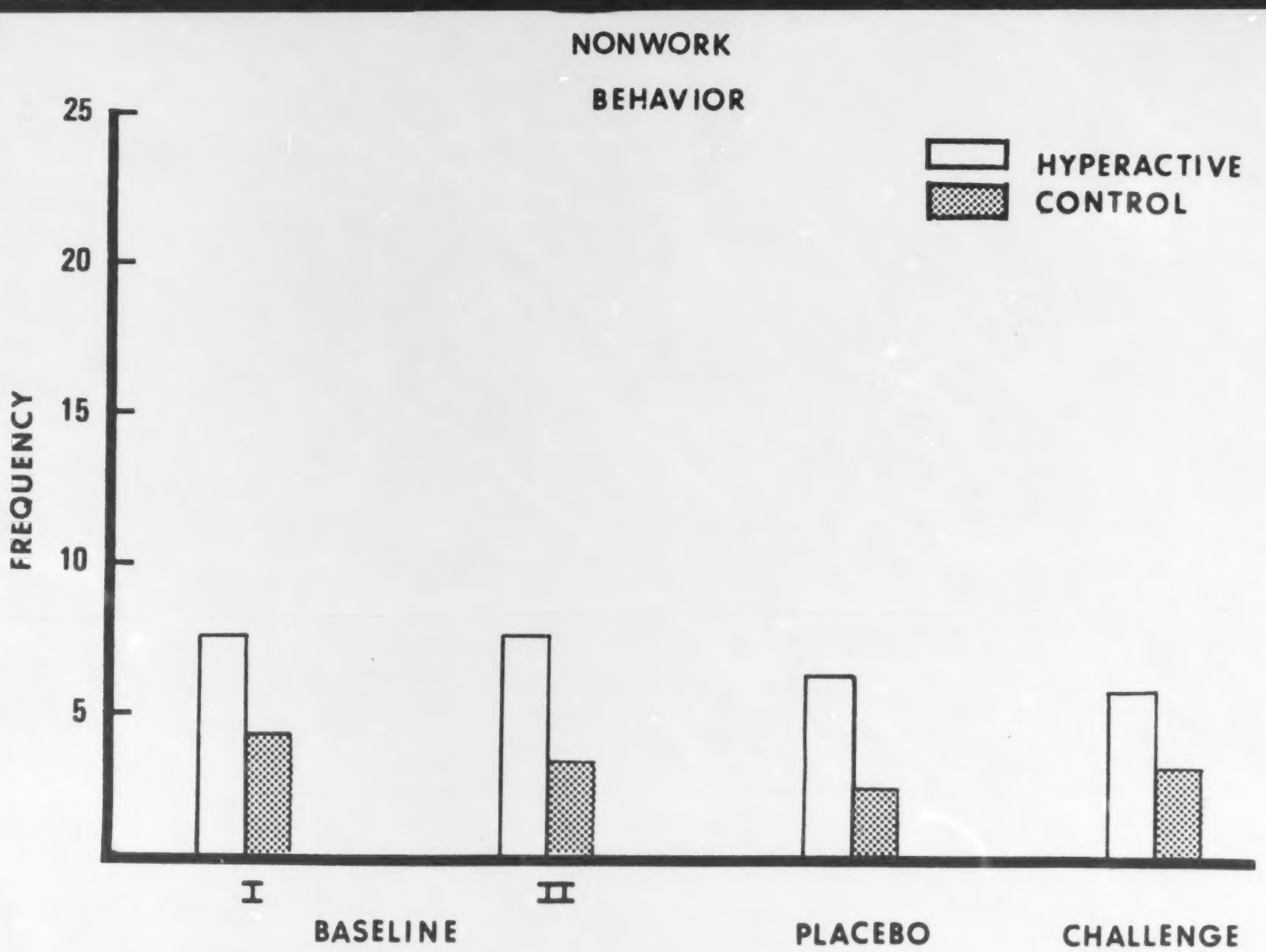

Figure 4.6 Mean Non-Work Classroom Behavior for the Hyperactive and Control Groups in Each Condition

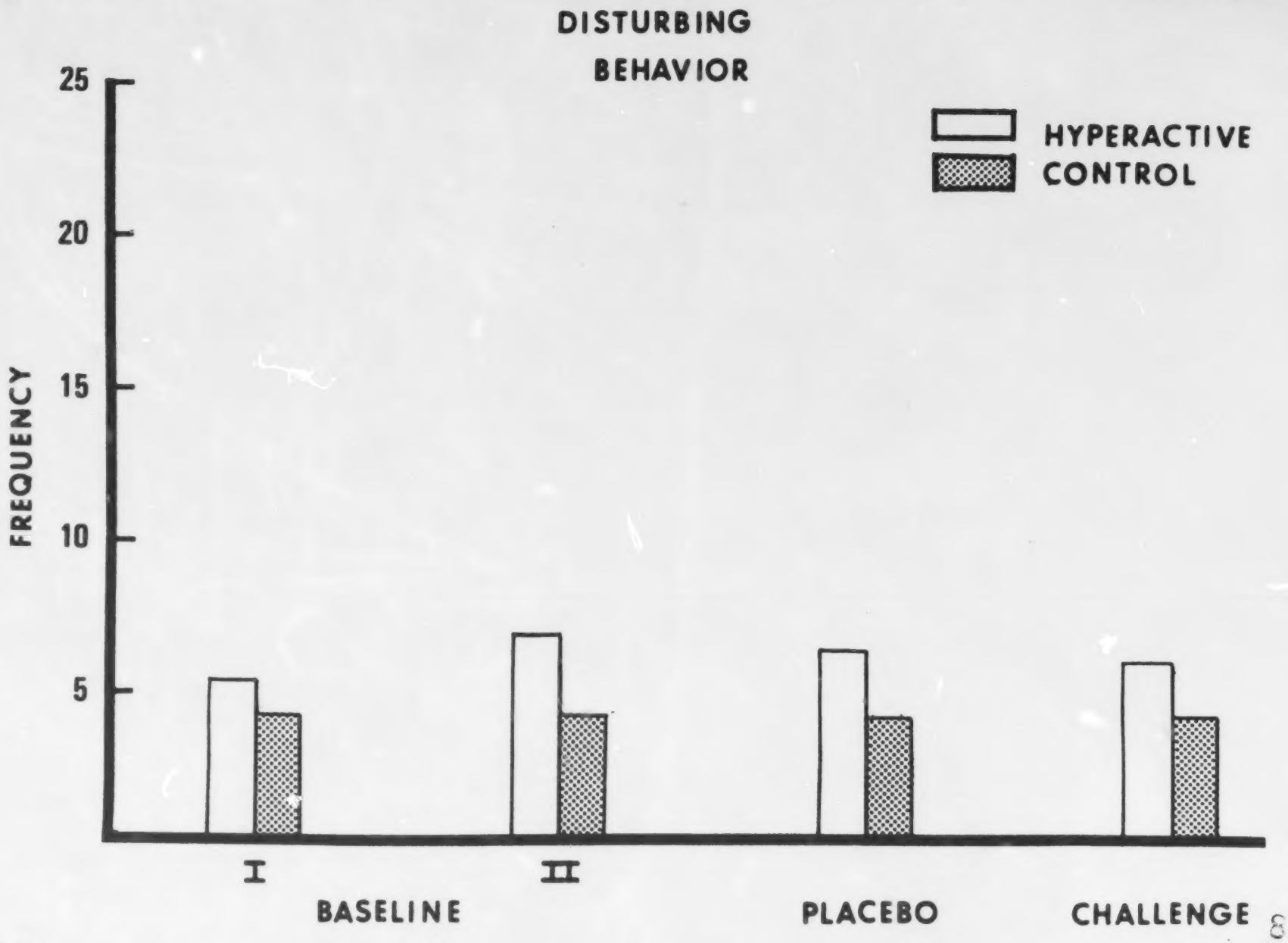

Figure 4.7 Mean Disturbing Classroom Behavior for the Hyperactive and Control Groups in Each Condition

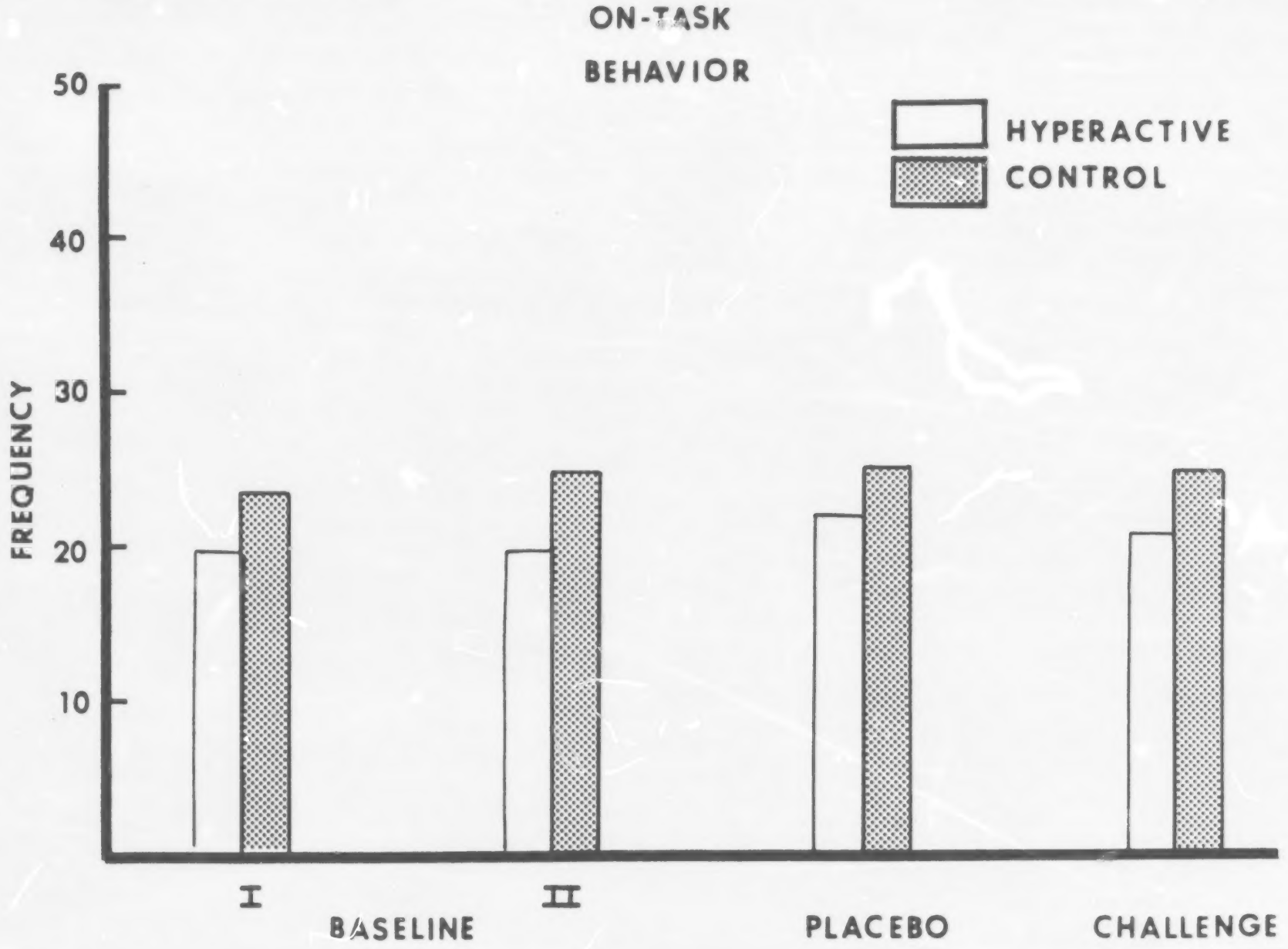

Figure 4.8 Mean On-Task Classroom Behavior for the Hyperactive and Control Groups in each Condition

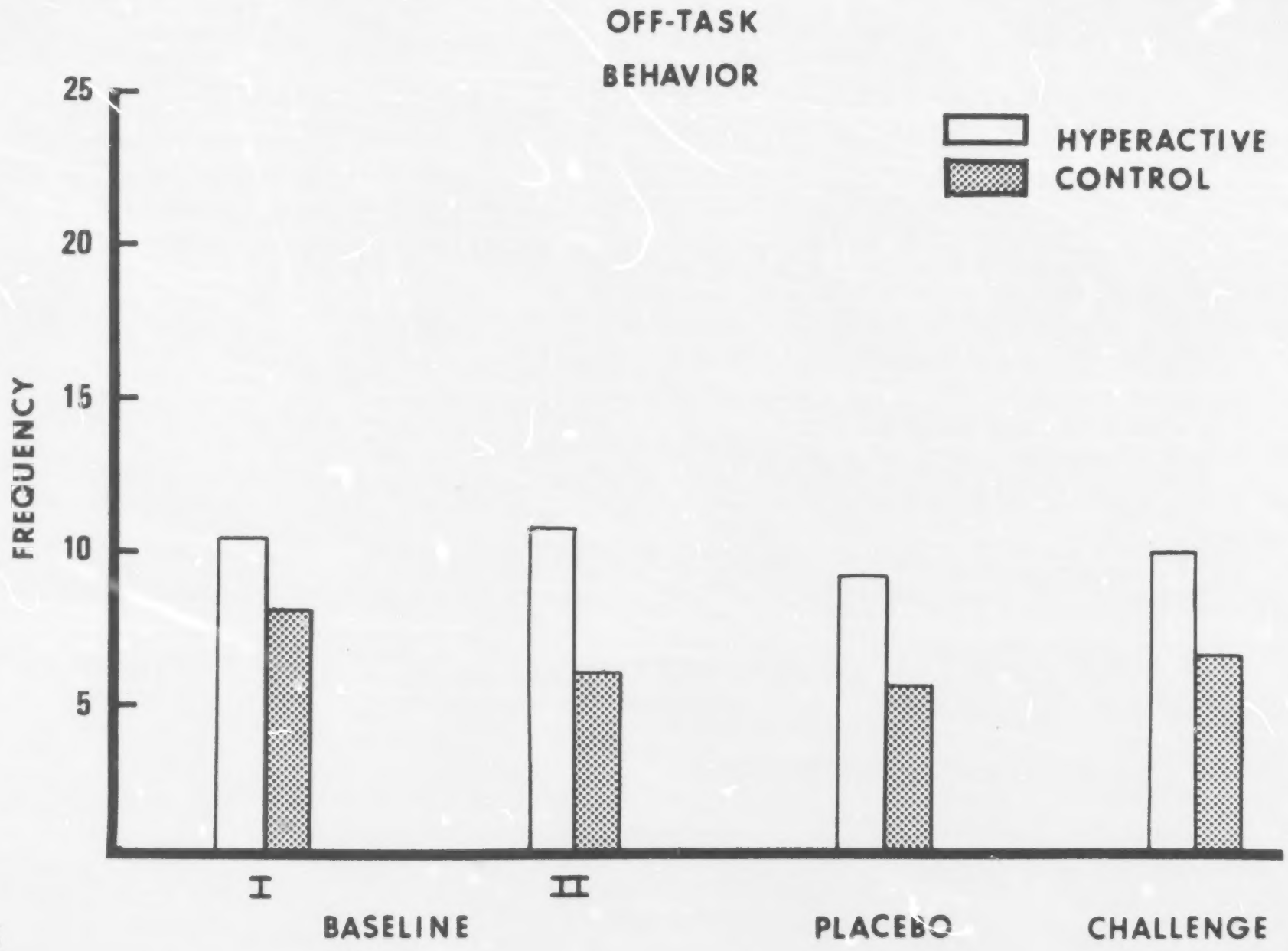

Figure 4.9 Mean Off-Task Classroom Behavior for the Hyperactive and Control Groups in Each Condition

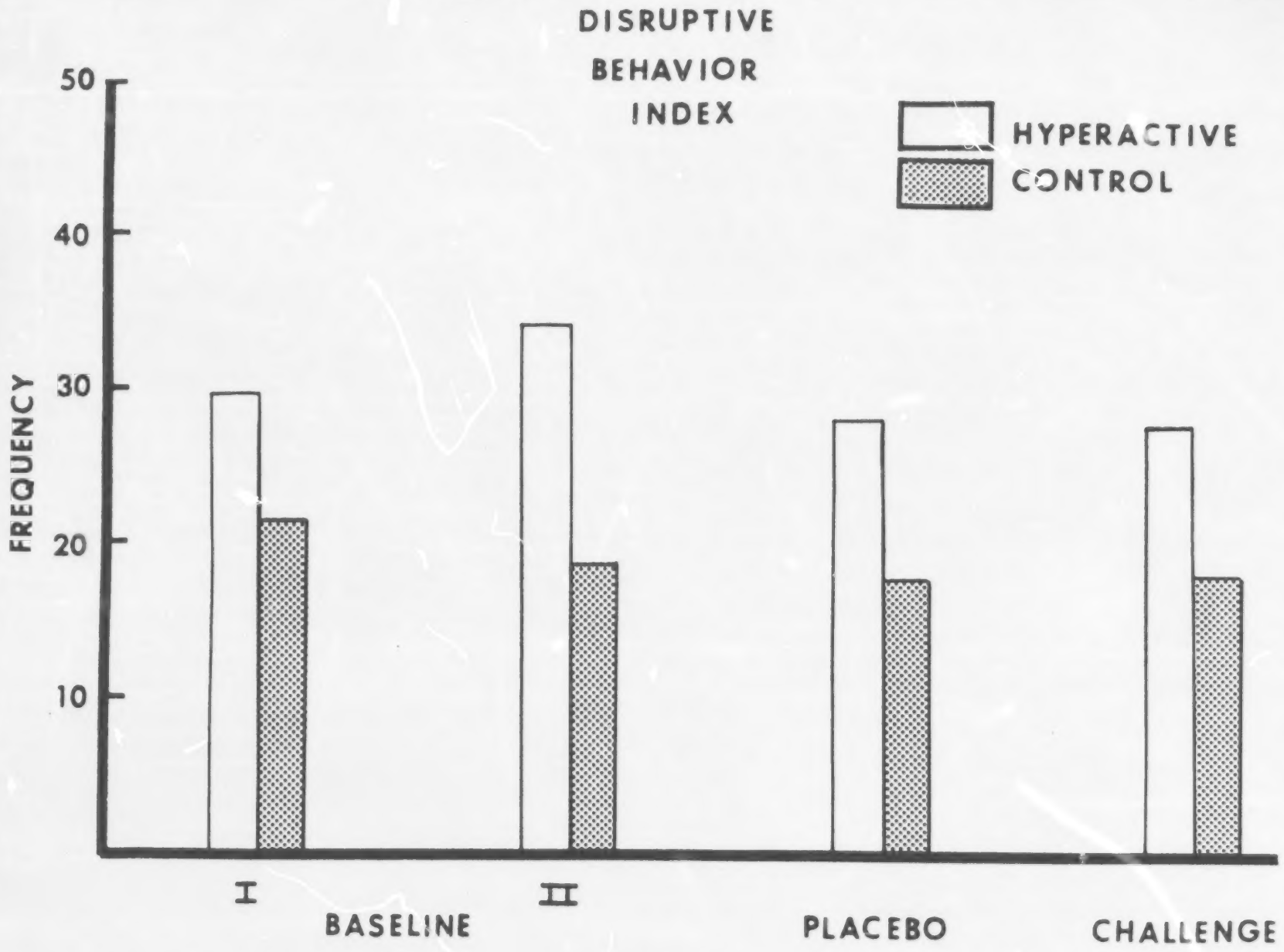

Figure 4.10 Mean Classroom Disruptive Behavior Index for the Hyperactive and Control Groups in Each Condition

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SECTION V - Individual Subject Data

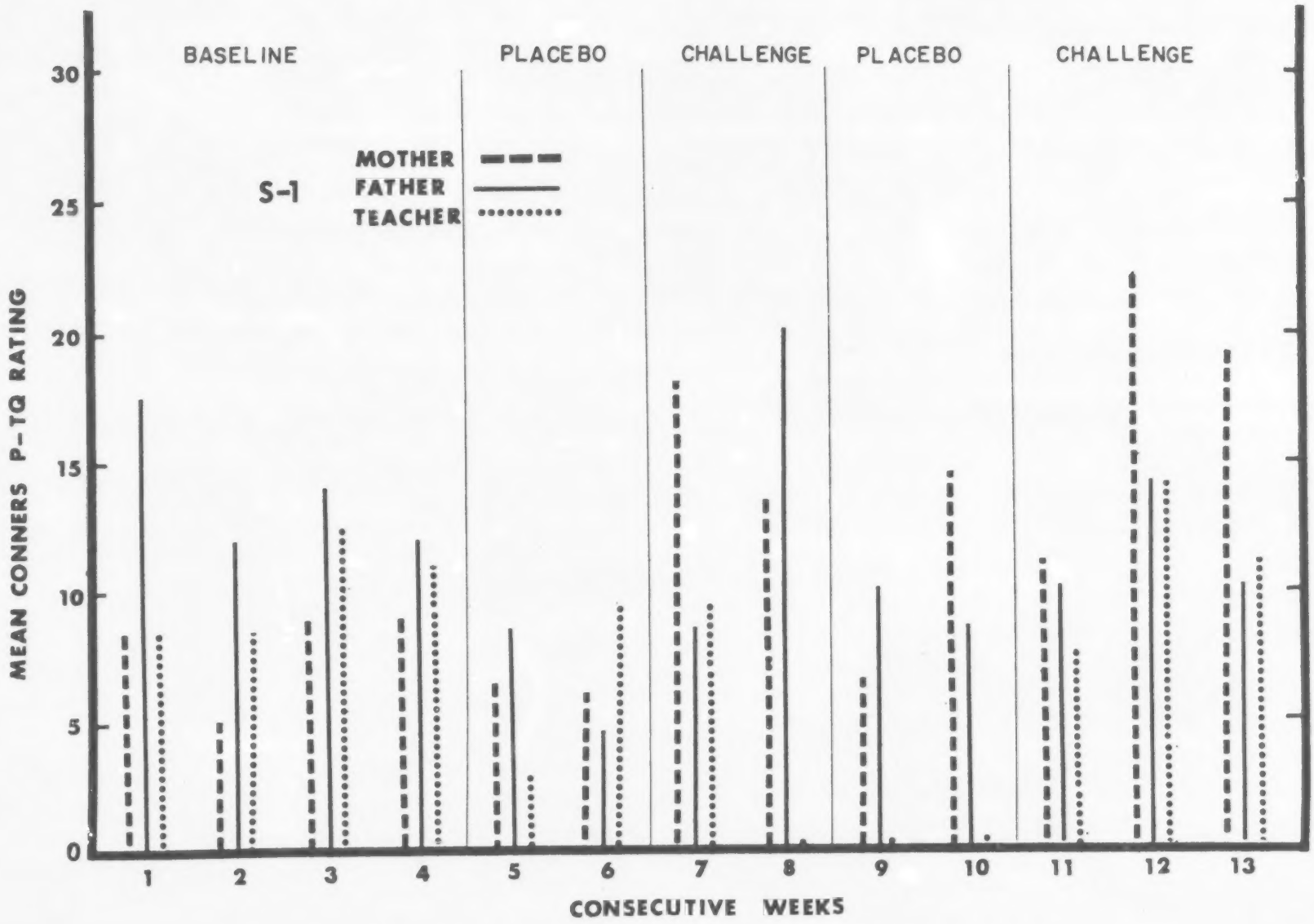
5.1 Conners P-TQ

The data analyses presented thus far were based upon group performance and rating information. Because this process of averaging the various dependent variables obscures individual information (Hersen and Barlow, 1976; Sidman, 1960), the question must be addressed if one or more than one individual demonstrated the changes in behavior which would be in accord with the challenge hypothesis. Therefore, the information presented in the present section depicts the P-TQ ratings (mother, father and teacher) for each of the nine hyperactive Ss separately (Figures 5.0 - 5.8). Careful examination of these figures indicates that none of the children demonstrated a precise placebo-challenge effect in their behavior as determined by the parent and teacher ratings. The one S who showed the "best" fit or closest approximation to the expected on-off effect was S-1. [Note: S-1's teacher gave him ratings of zero on the P-TQ for weeks 8-10.] The remainder of the Ss failed to demonstrate comparable behavioral changes corresponding to the treatment conditions.

Two Ss (S-3 and S-9) had to be placed on medication during the course of the experiment. In both cases the child's behavior deteriorated at school and home to a degree that necessitated returning the child to his prior medication program. (Only data collected prior to medication were incorporated in the group statistical analyses.) The code was not broken in these two cases, but rather the children were maintained on the K-P diet, while taking their medication. At the conclusion of the study it was learned that these two Ss exhibited their worst behavior during the placebo (no artificial food colors) rather than during the color challenge condition.

5.2 Classroom Behavior

Figures 5.9 - 5.17 illustrate the index of disruptive classroom behavior (sum of motor, disturbing, non-work and off-task behavioral categories) for the nine hyperactive Ss for each of the 13 weeks of the study. Again, inspection of the individual figures fails to show substantial behavioral changes in the classroom associated with the placebo and challenge manipulations.



91 Figure 5.0 S#1 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher 92

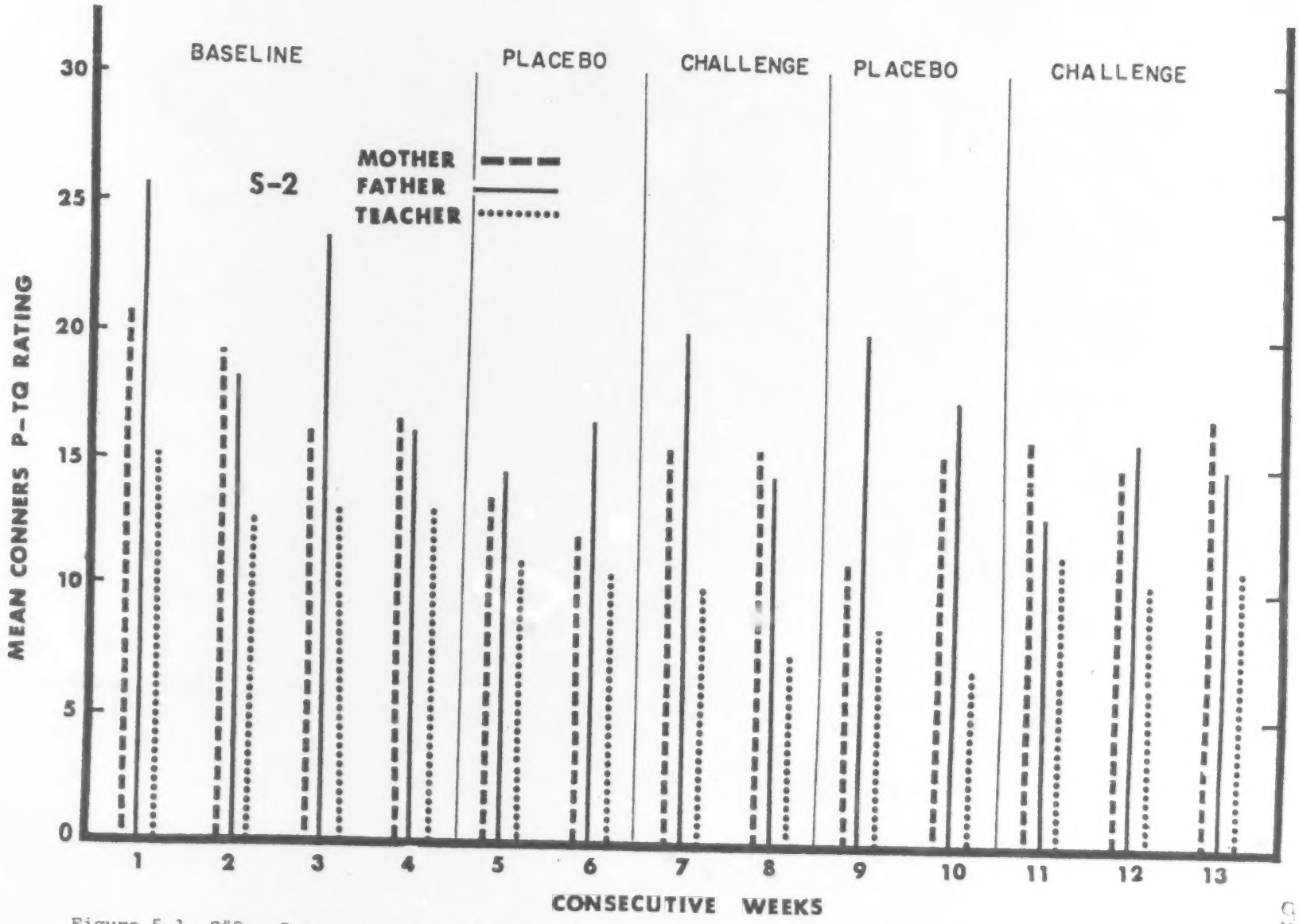


Figure 5.1 S#2 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher

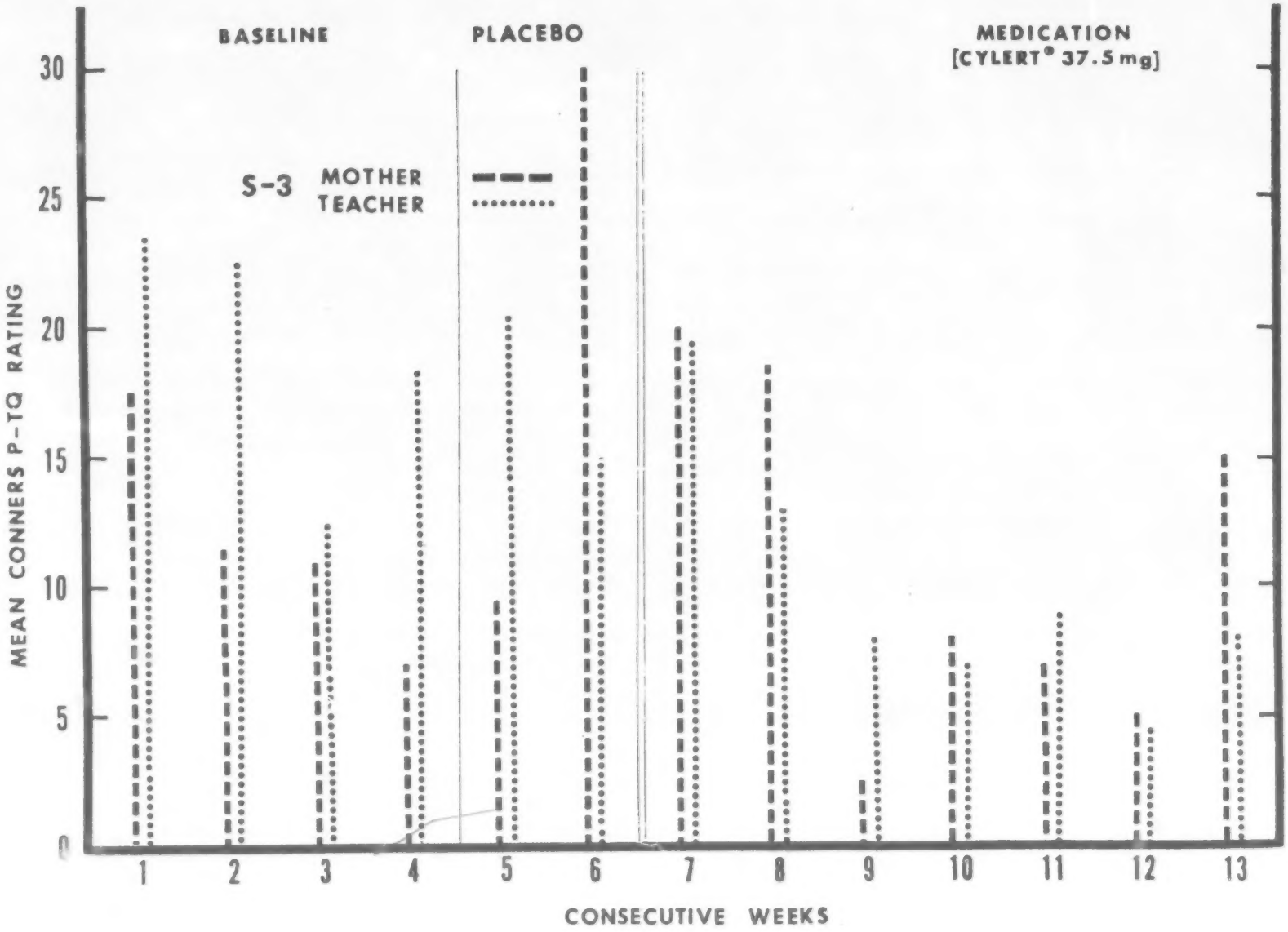


Figure 5.2 S#3 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher

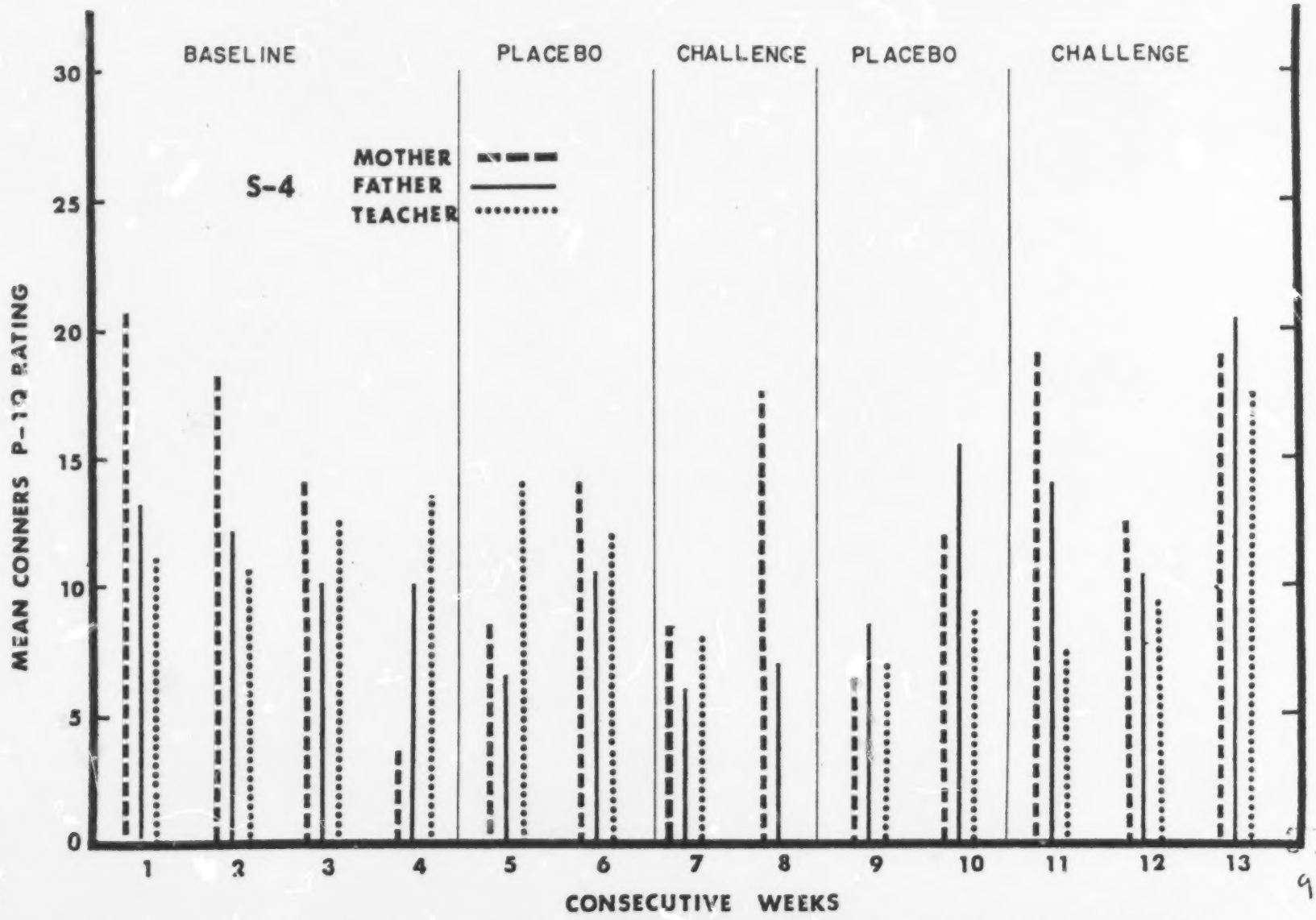


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Figure 5.3 S#4 - Consecutive Mean Weekly Conners P-10 Ratings Made by Mother, Father and Teacher

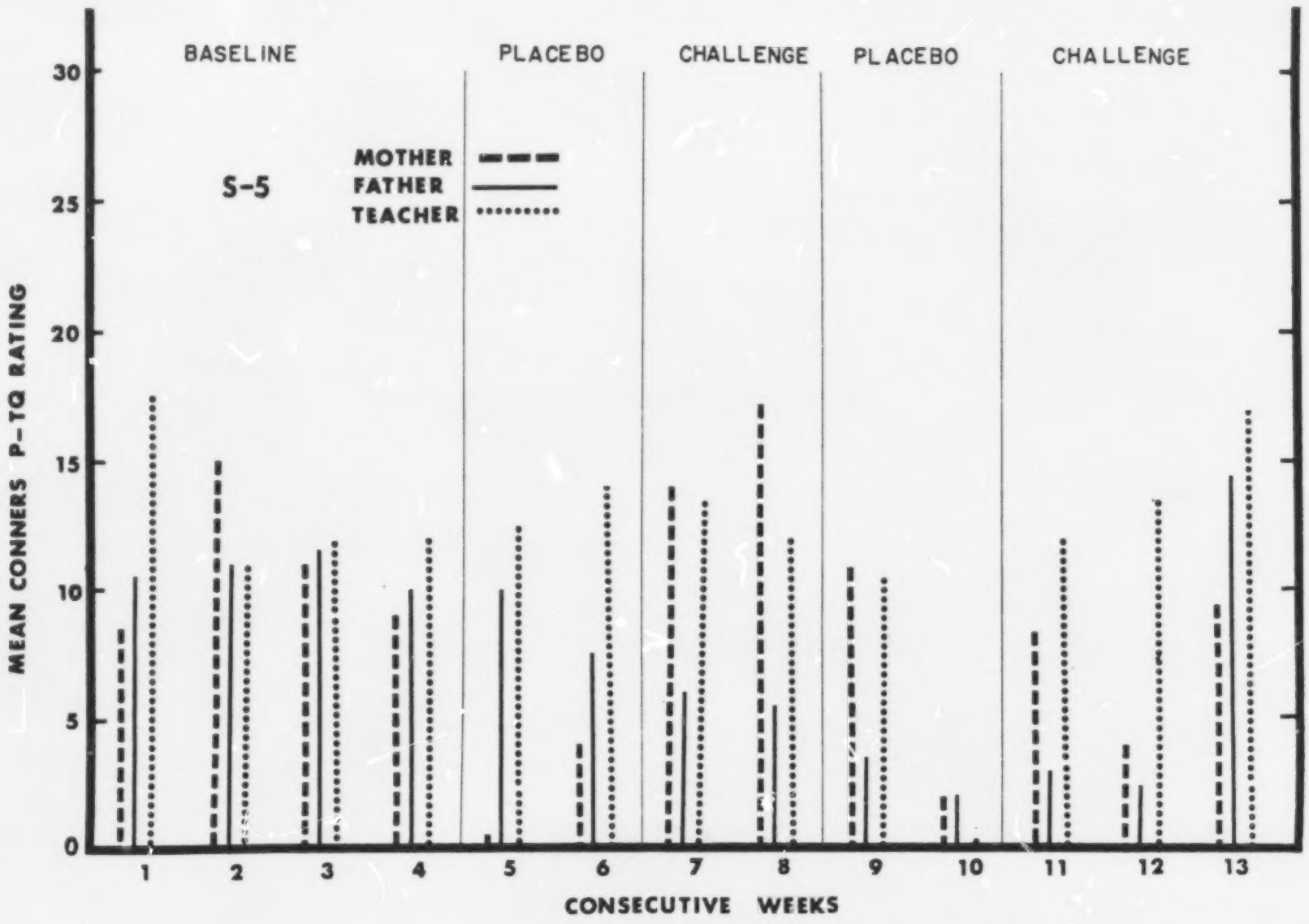


Figure 5.4 S#5 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher

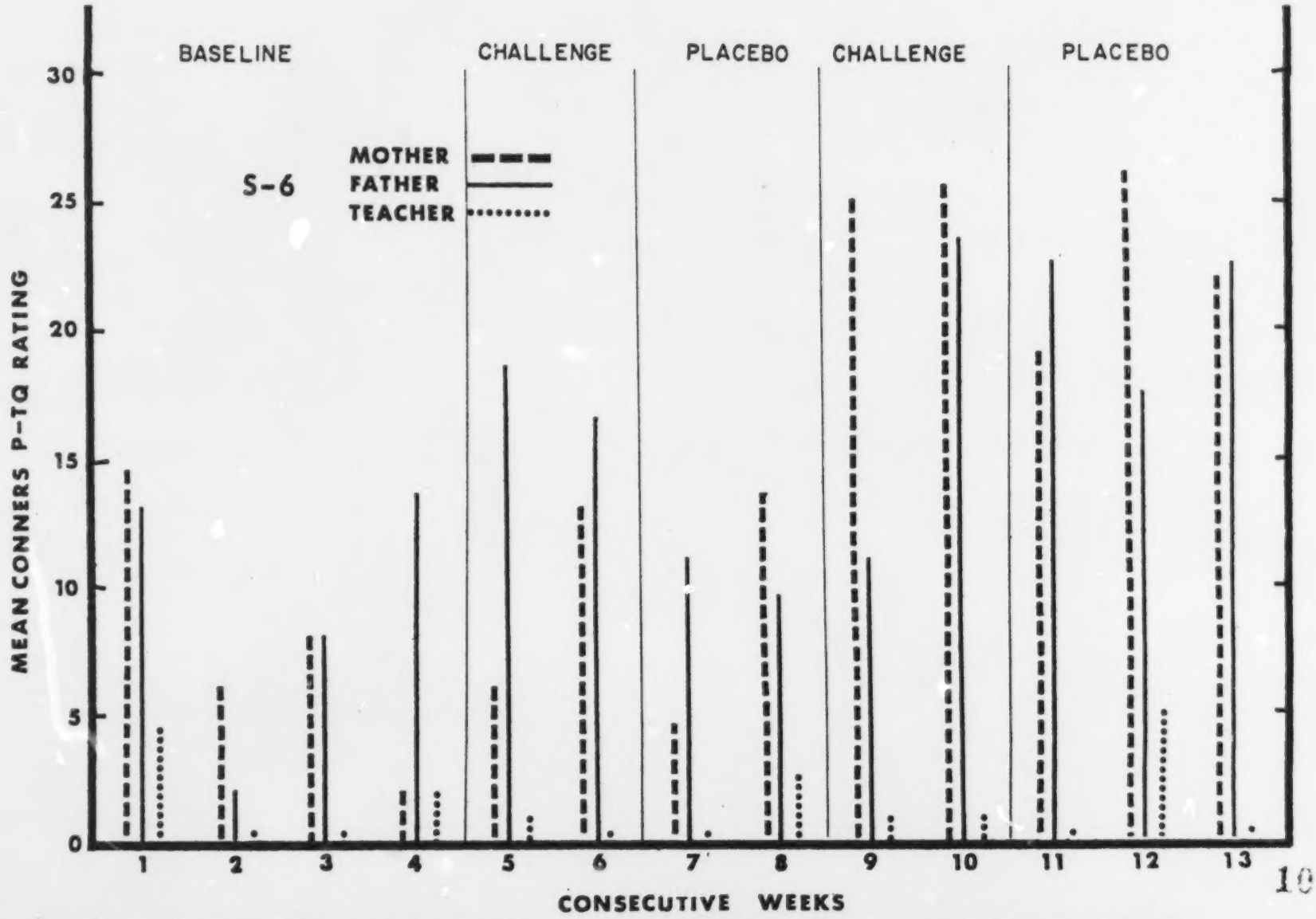
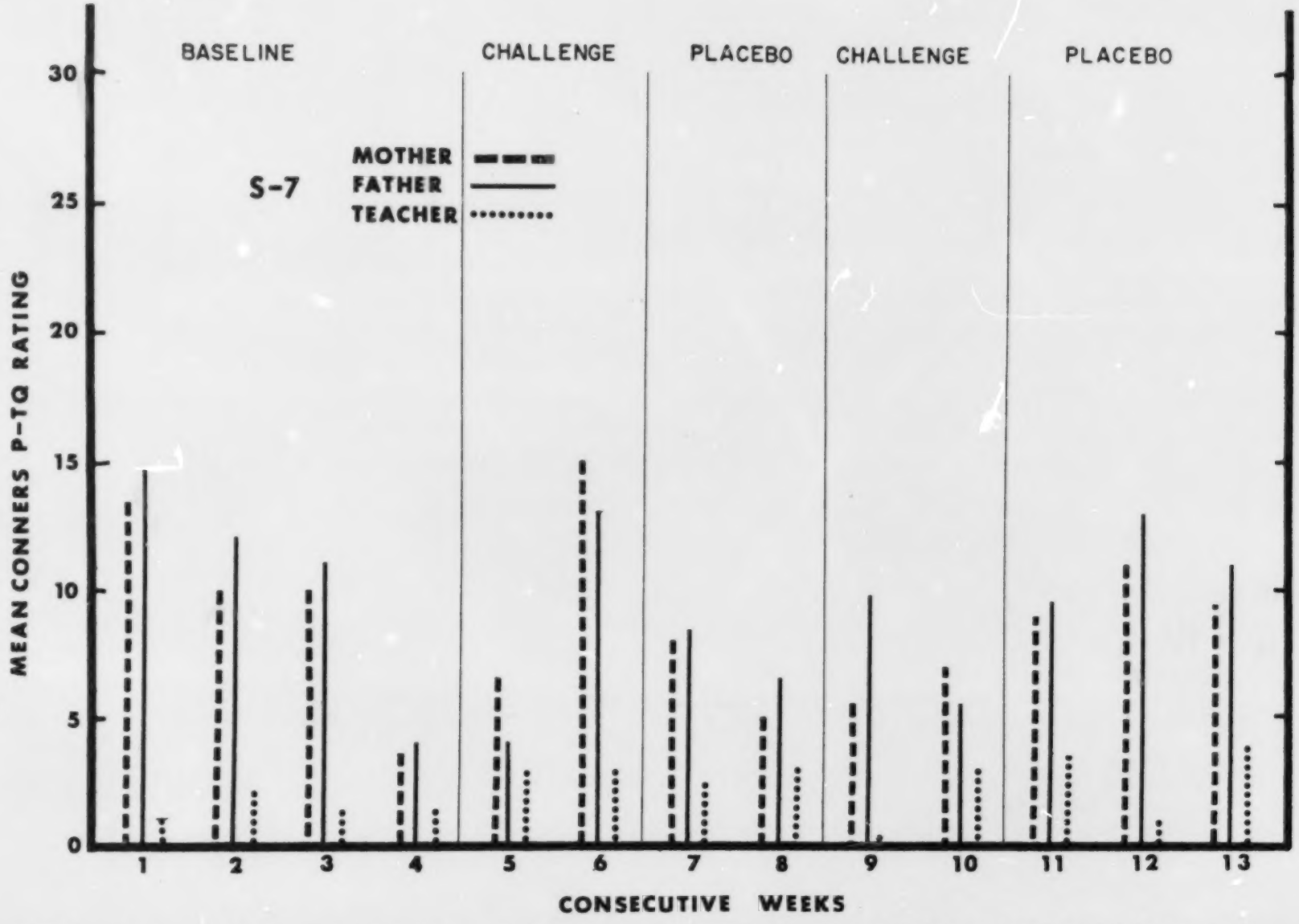


Figure 5.5 S#6 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher



103 Figure 5.6 S#7 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher 104

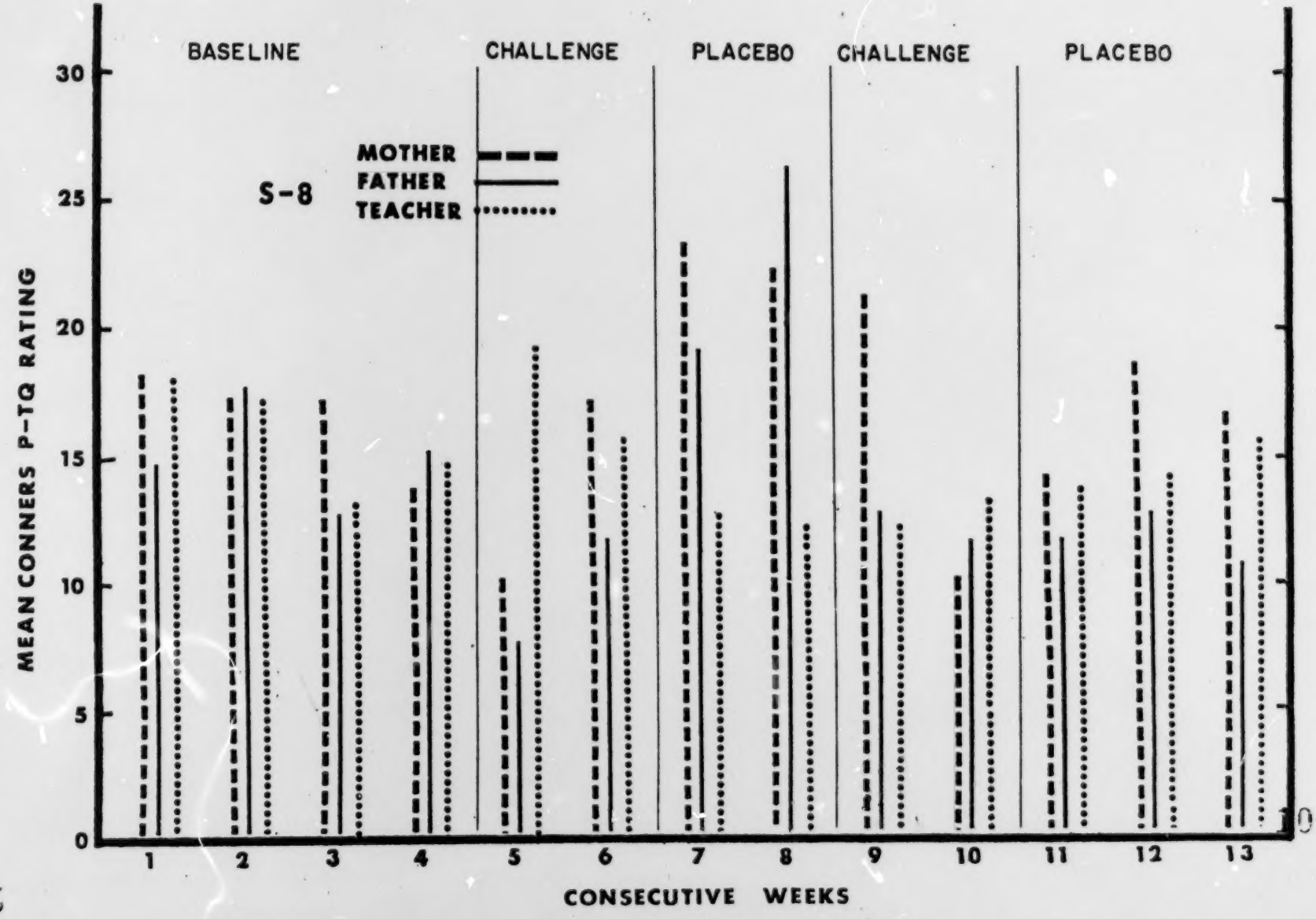


Figure 5.7 S#8 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher

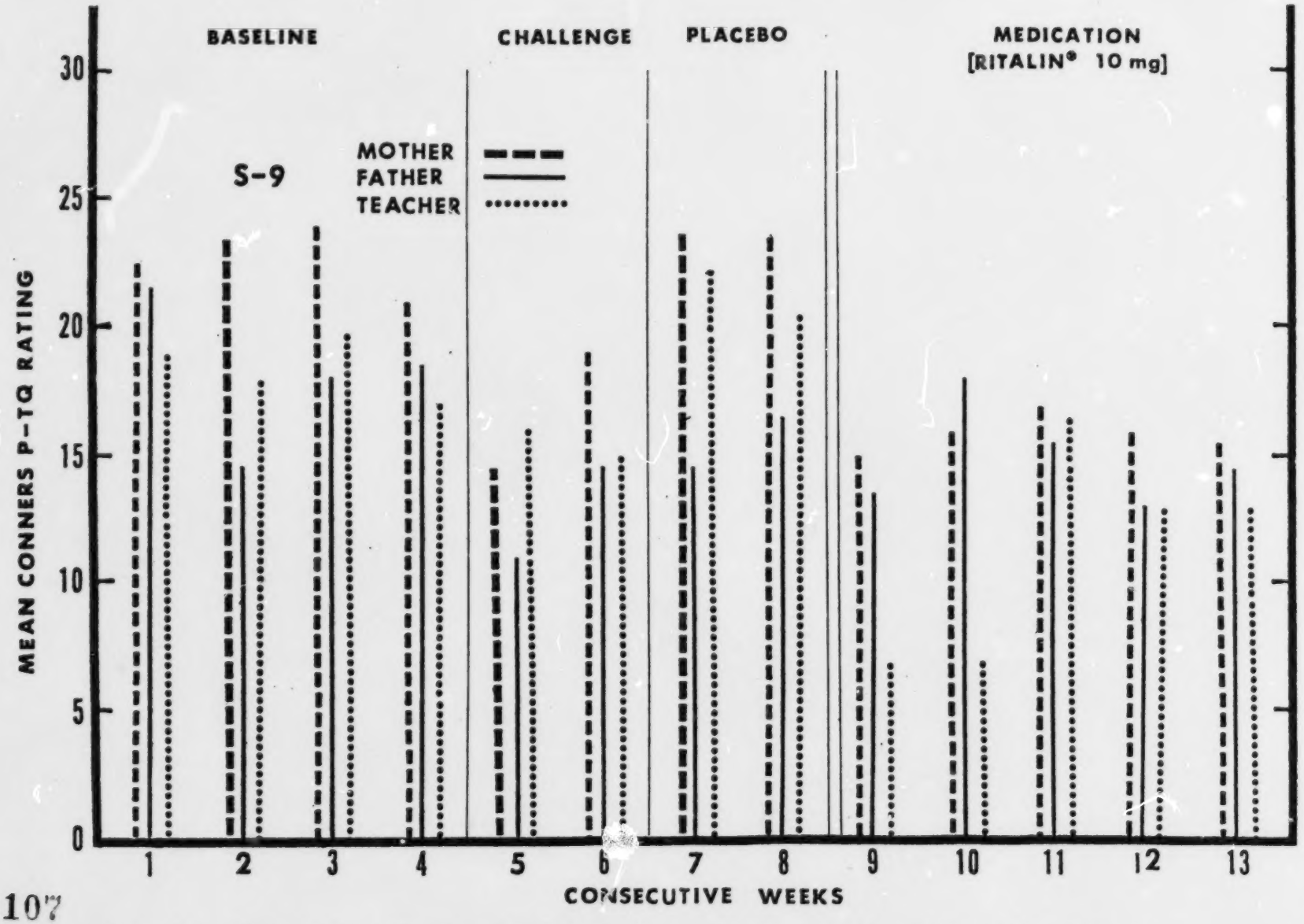


Figure 5.8 S#9 - Consecutive Mean Weekly Conners P-TQ Ratings Made by Mother, Father and Teacher

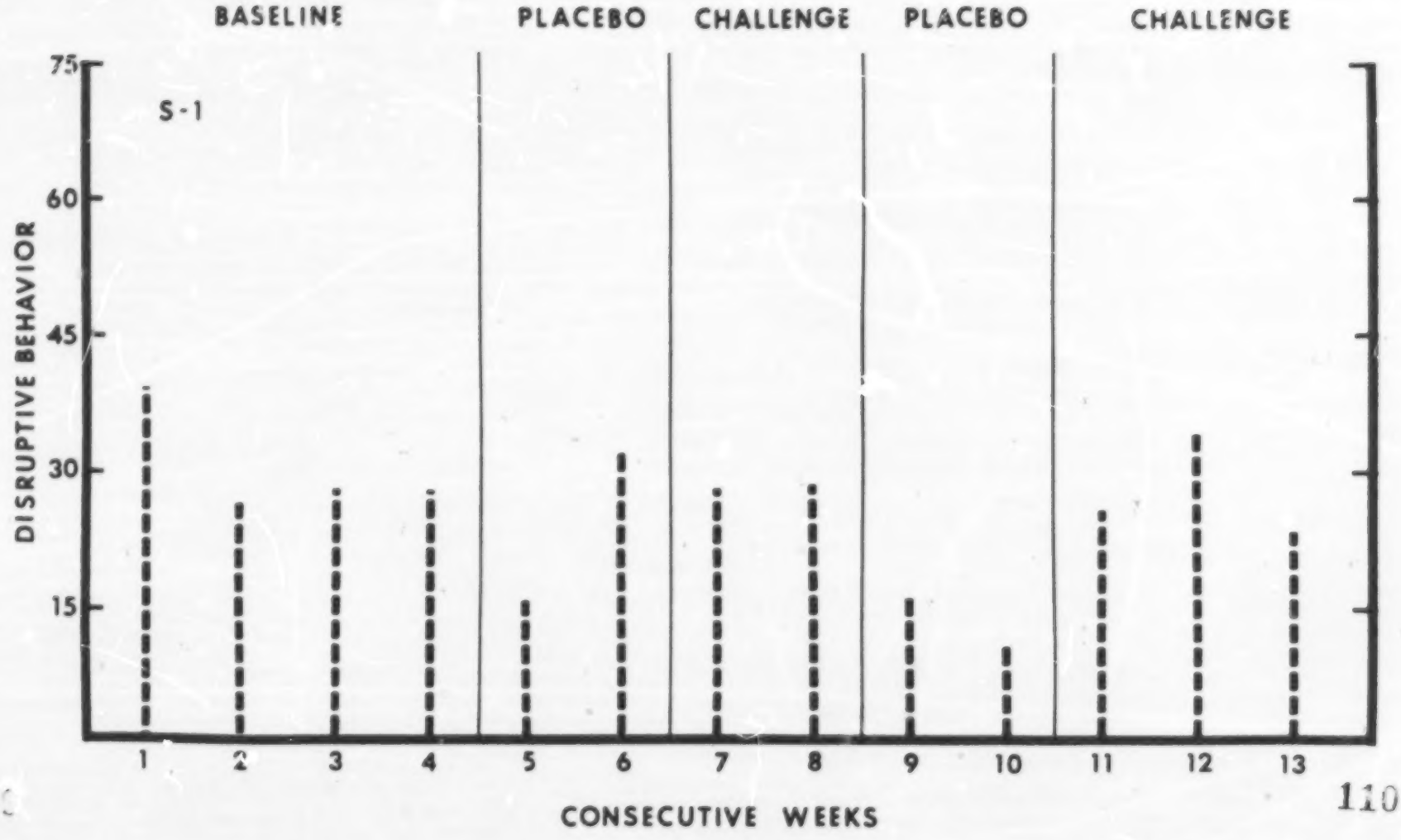


Figure 5.9 S#1 - Weekly Mean Classroom Disruptive Behavior Index

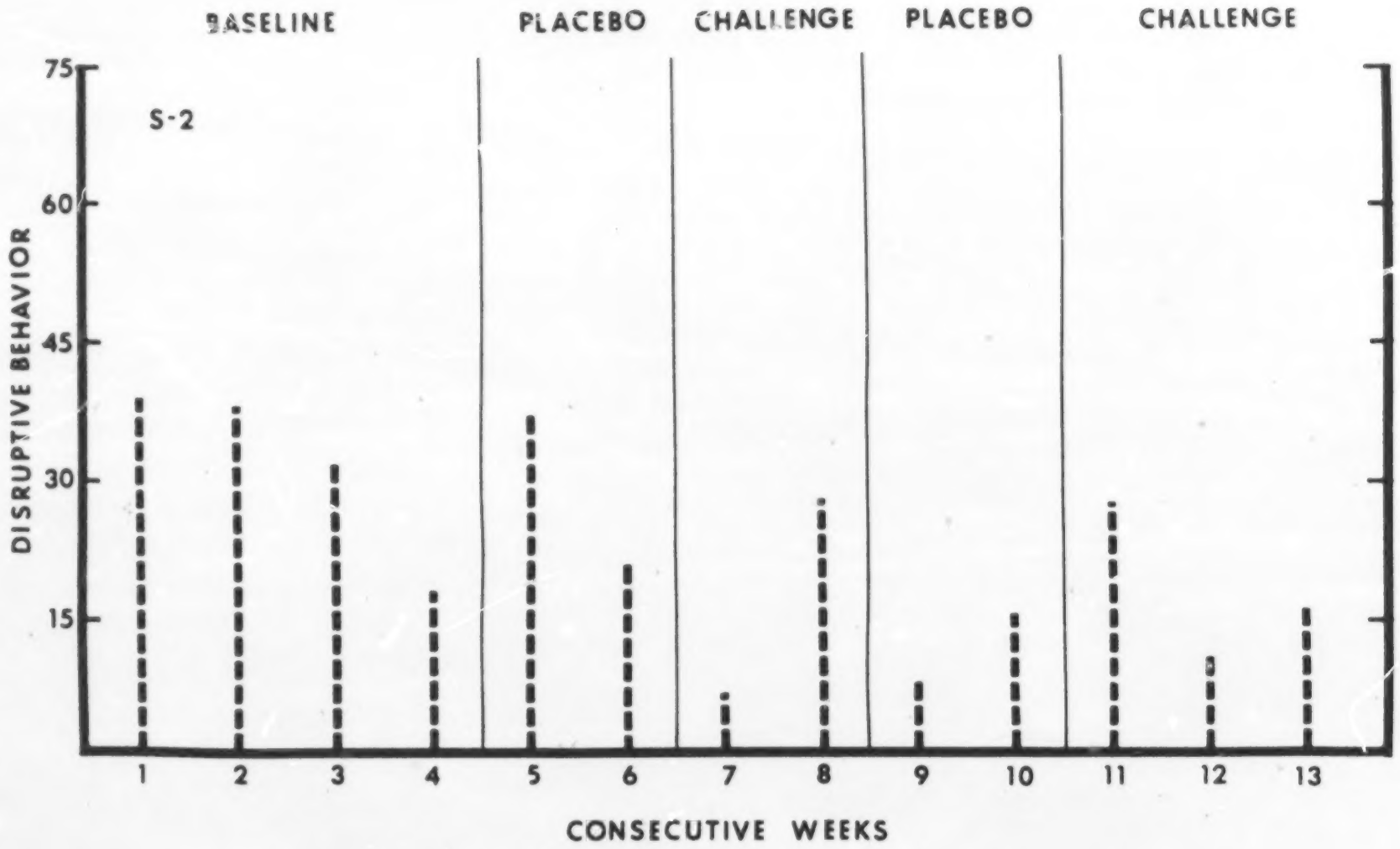


Figure 5.10 S#2 - Weekly Mean Classroom Disruptive Behavior Index

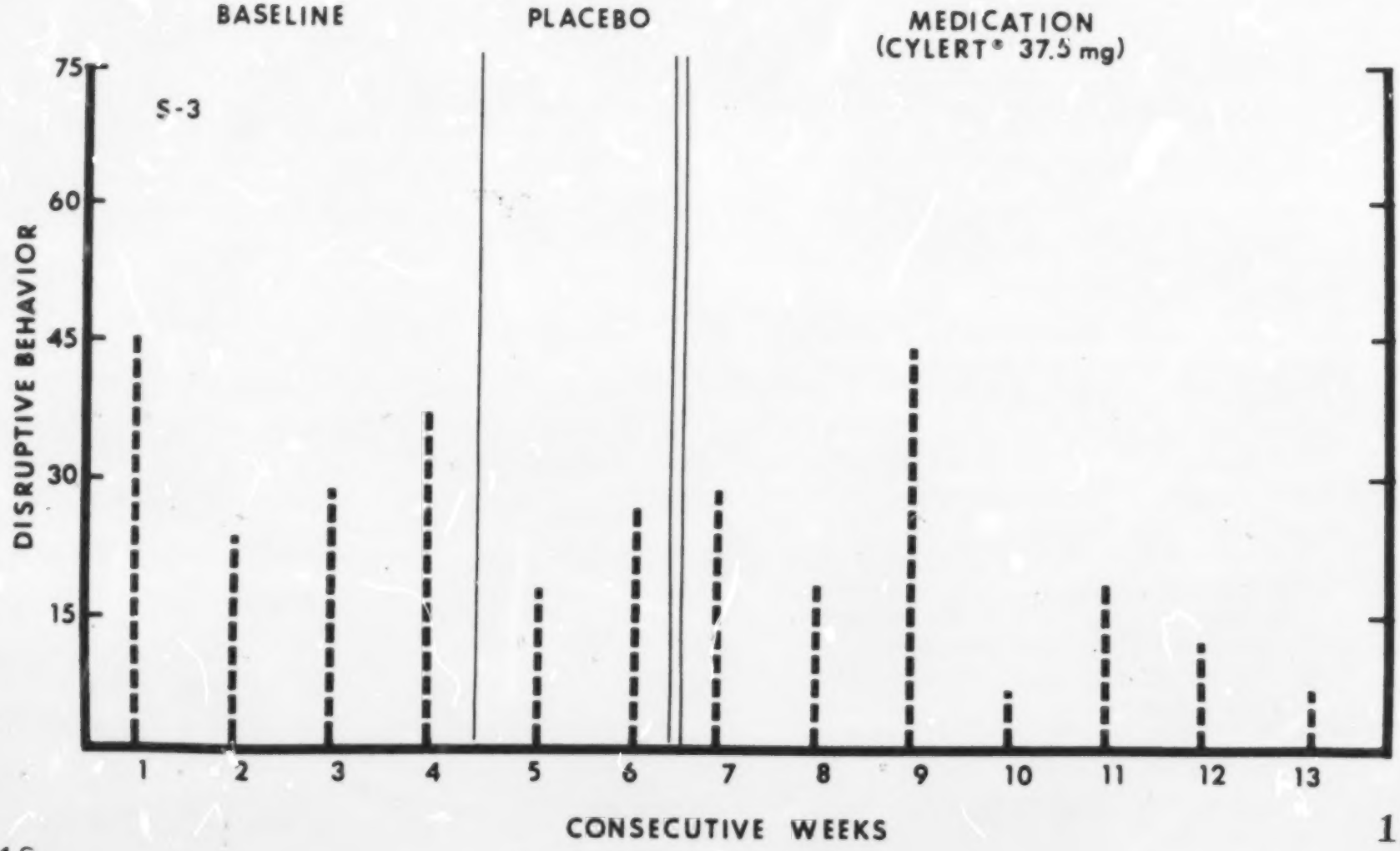


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Figure 5.11 S#3 - Weekly Mean Classroom Disruptive Behavior Index

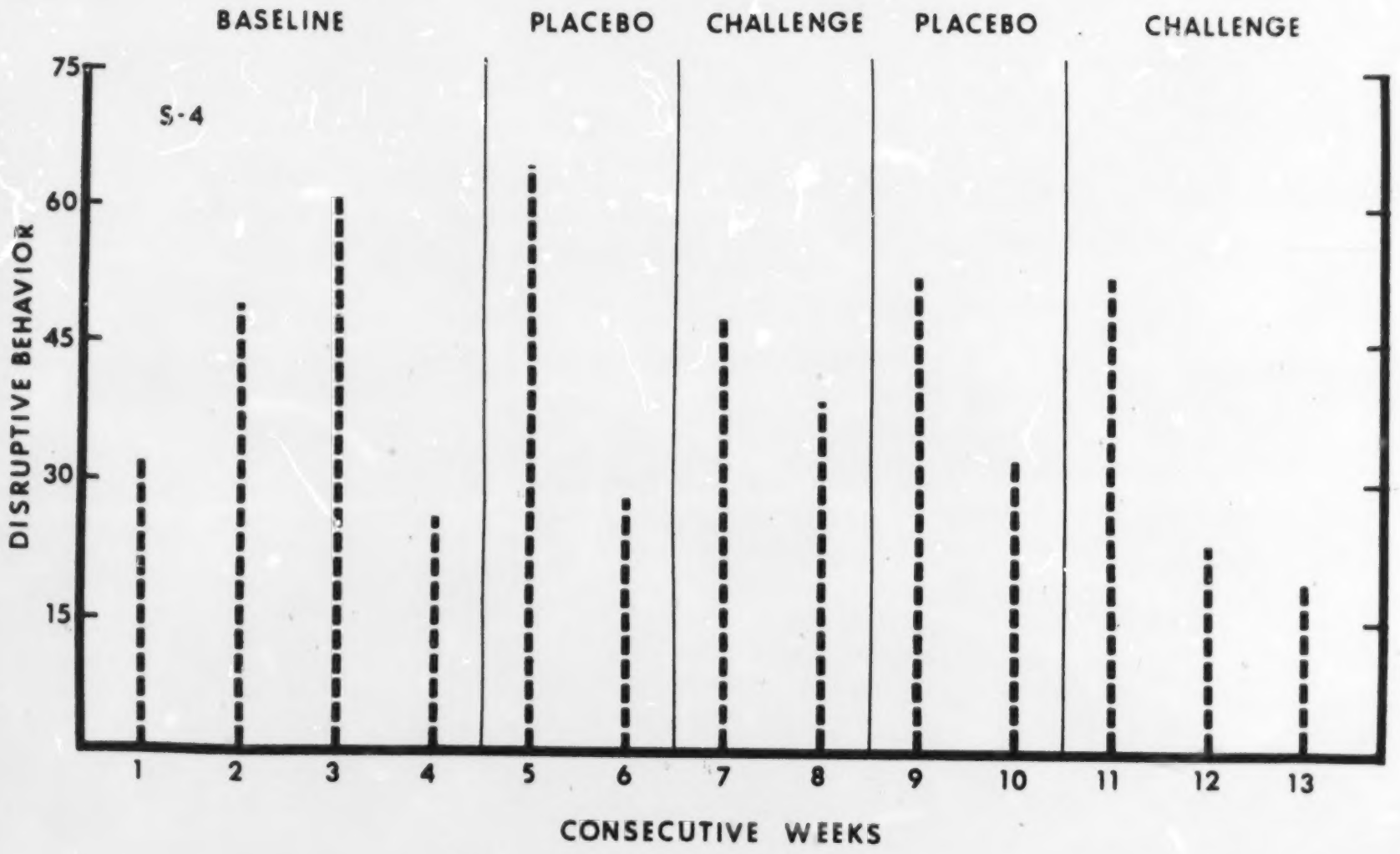

Figure 5.12 S#4 - Weekly Mean Classroom Disruptive Behavior Index

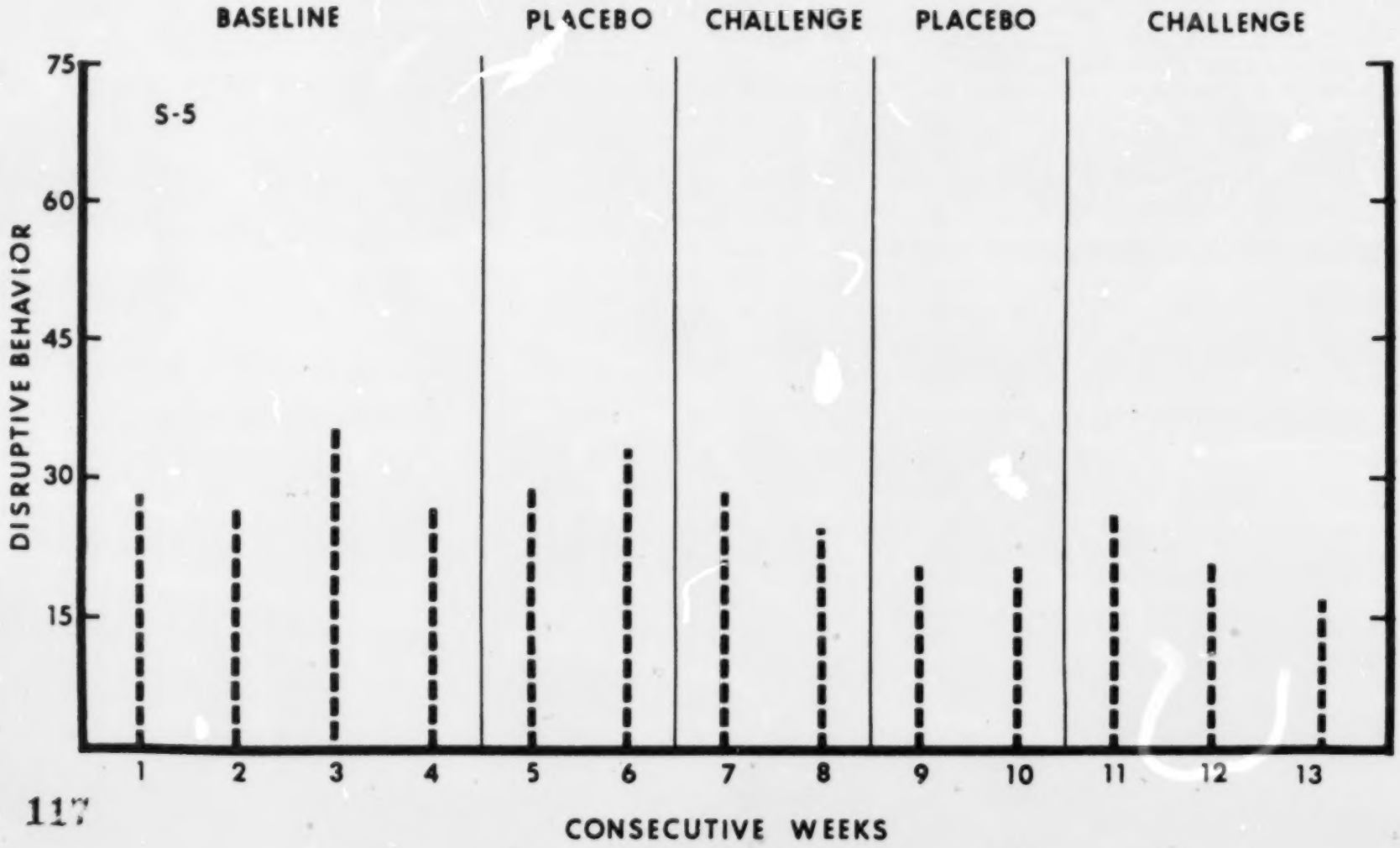

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Figure 5.13 S#5 - Weekly Mean Classroom Disruptive Behavior Index

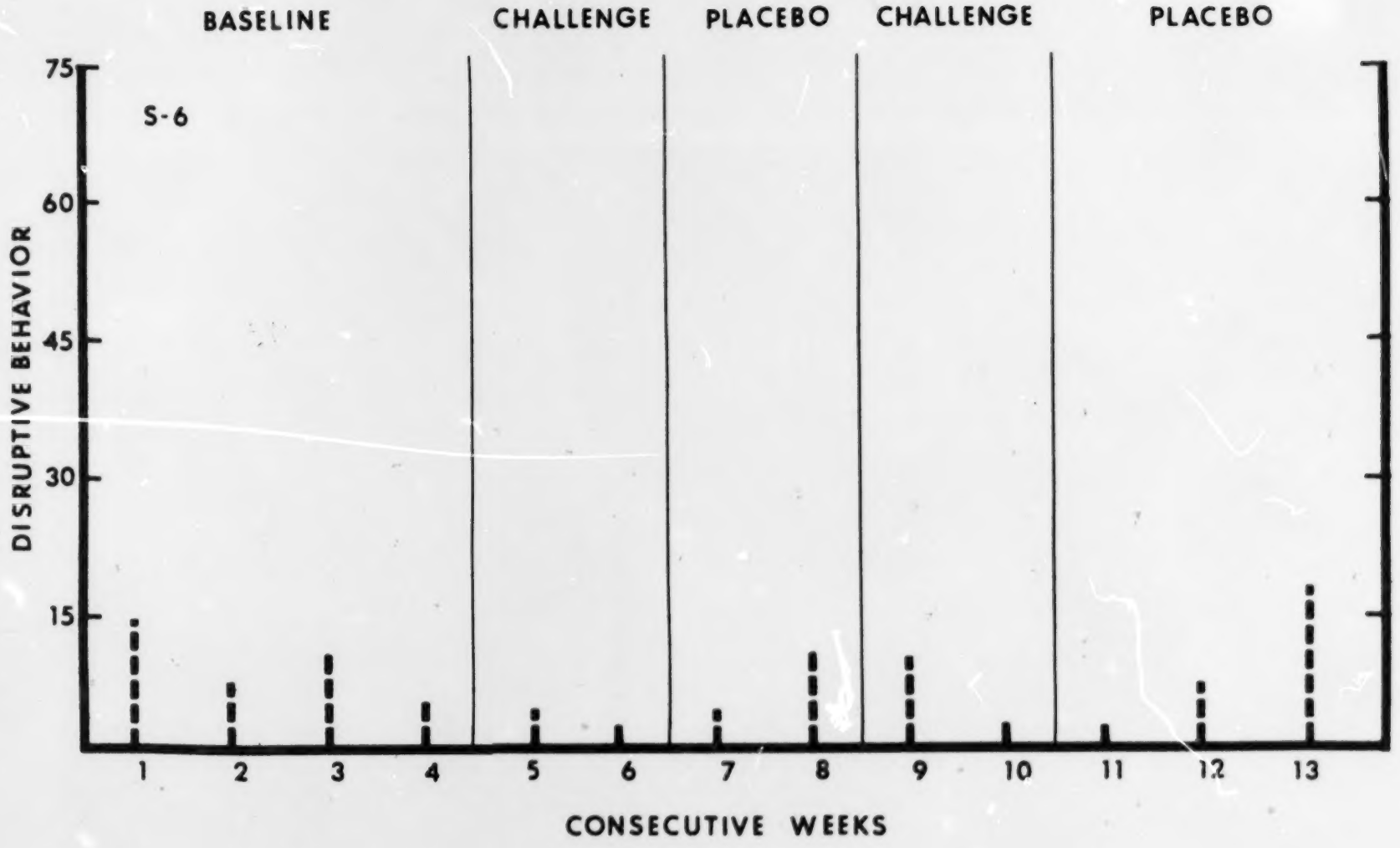

Figure 5.14 S#6 - Weekly Mean Classroom Disruptive Behavior Index

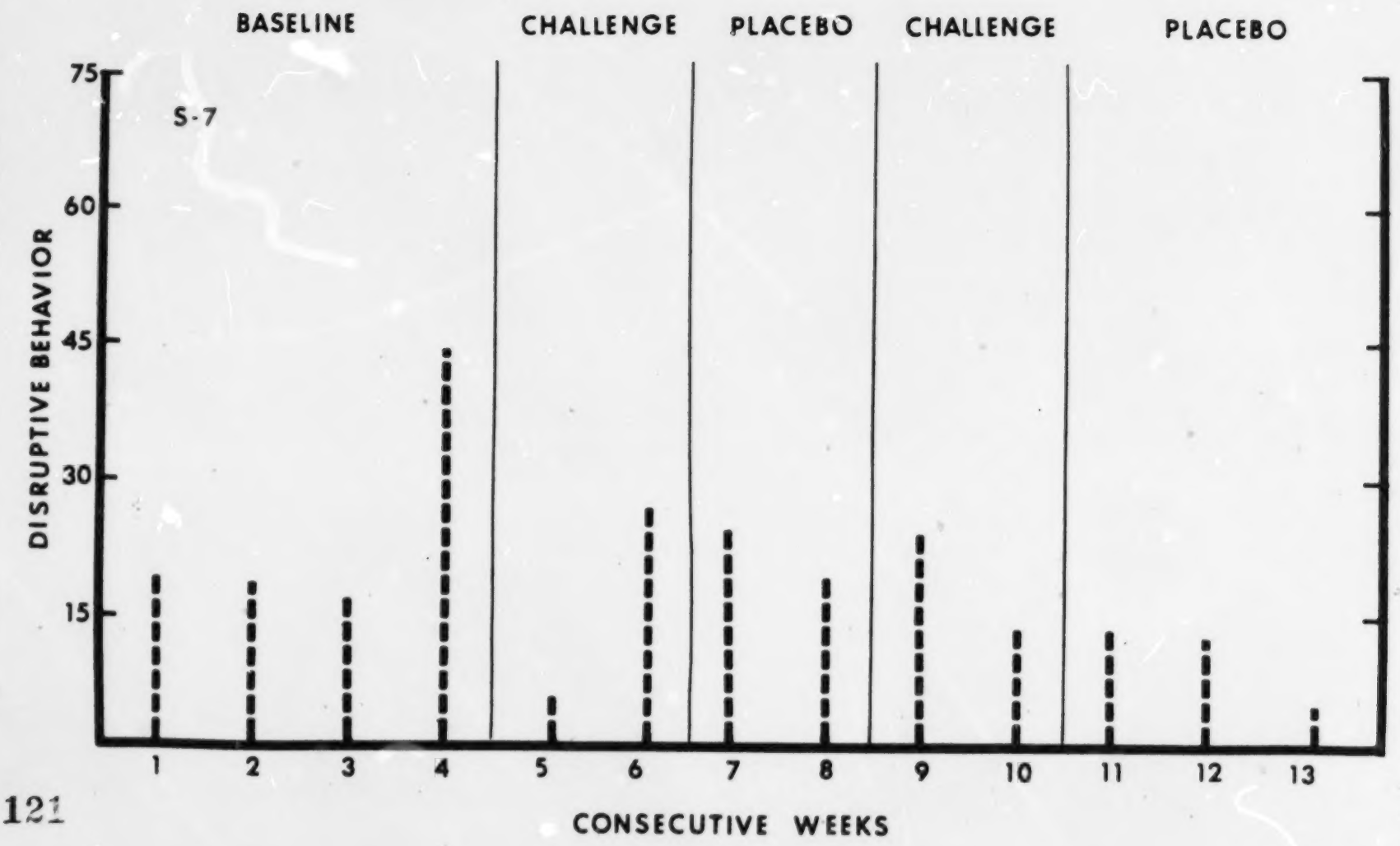

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Figure 5.15 S#7 - Weekly Mean Classroom Disruptive Behavior Index

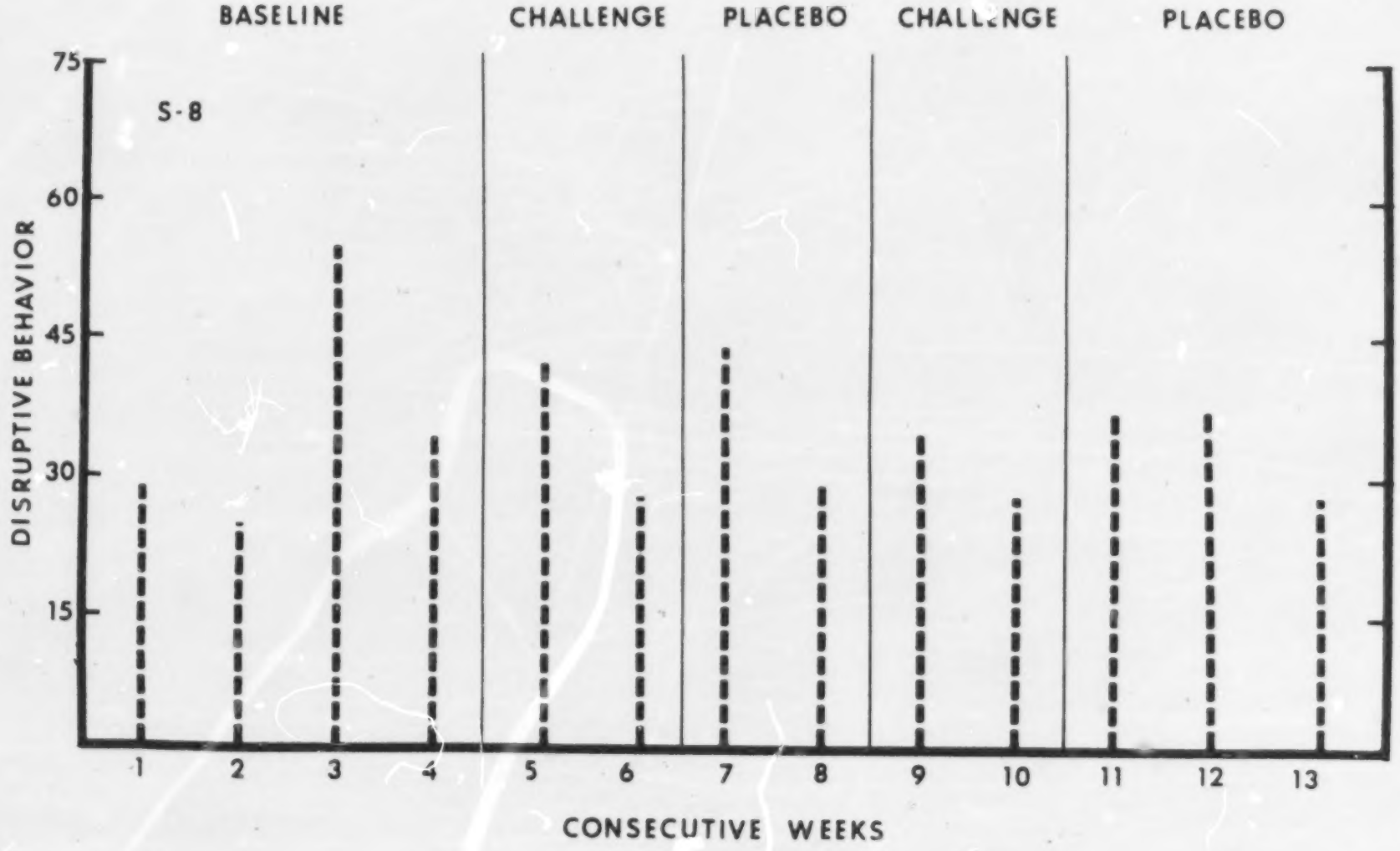

Figure 5.16 S#8 - Weekly Mean Classroom Disruptive Behavior Index

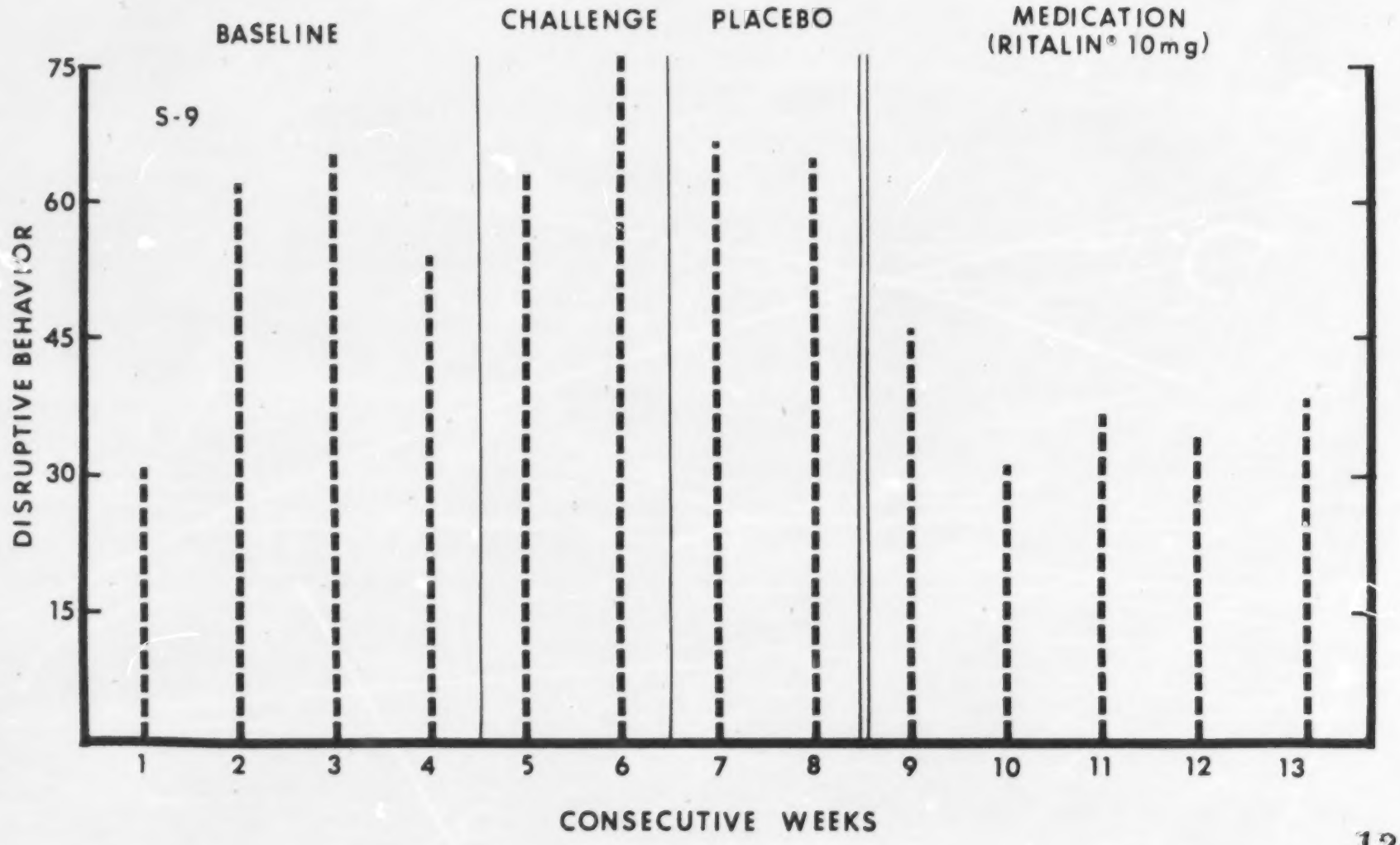

Figure 5.17 S#9 - Weekly Mean Classroom Disruptive Behavior Index

SECTION V: REFERENCES

Hersen, M. and Barlow, D. H. Single-case Experimental Designs: Strategies for Studying Behavior Change. New York: Pergamon Press, 1976.

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SECTION VI - Discussion

Feingold has observed that if a child deviates from his elimination diet (i.e. one free of foods containing synthetic flavors and colors and salicylates), ingestion of even minute amounts of the proscribed foods (e.g., a stick of gum, a cookie or soft drink) "causes a recurrence of the complete behavioral pattern within two to four hours which persists for one to four days." (1975, p. 801). The overall results of the present challenge study do not provide confirmatory experimental data for these clinical observations.

Conners and Goyette (1977) have reported preliminary results of two challenge studies incorporating food containing the certified food colors. The authors did not find a change in hyperactive symptoms related to the challenge versus placebo treatments in the first study. A performance decrement on an attention task, however, was found shortly after ingestion of the challenge materials, suggesting some kind of transient psychopharmacological effect. A second study by Conners and Goyette using a group of preschool children suggested a possible deleterious behavioral effect of synthetic food colorings in this younger age group, an observation which is in accord with the results of the Phase I study by the Wisconsin Investigative Team (1977).

In another double-blind, crossover experiment (Spring, Vermeersch, Sterling and Blunden, 1978) six hyperactive male children were given chocolate cookies provided by the Nutrition Foundation. Each S ingested both challenge cookies (containing a blend of the average daily amount of artificial colors) and placebo cookies (no synthetic food additives). The six Ss were randomly assigned to one of two conditions. One group was challenged in weeks 1 and 4, and in the other condition Ss received the challenge cookies in weeks 3 and 6 of the six week experimental period.

The authors tentatively concluded (replication pending) that one child showed an exacerbation of hyperactivity following ingestion of synthetic food colors as indicated by his mother's and teacher's ratings on a behavior questionnaire highly similar to the Conners P-TQ. Additional data were interpreted as indicating that the K-P diet evokes a placebo response from the mothers.

Following a review of the scientific literature relevant to the Feingold hypothesis, Spring and Sandoval (1976) concluded that "public advocacy has far outstripped the research on which it should be based." The authors also challenged the prevalence estimates of hyperkinesis and the causal relationship between amount of food additives and the increase in the incidence of hyperkinesis over the last decade inferred by Feingold (1975), presenting evidence which did not support Feingold's impression that there has been a substantial increase in hyperactivity-learning disabilities over the last ten years, rather than just an increased awareness of the disorder. Feingold (1975) acknowledges that "hyperkinesis is still not understood despite the tremendous volume of basic research and clinical observations on it" (p. 797-798) and that incidence figures vary widely, depending upon the source.

The recommended use of the K-P diet program, however, has not been limited to the treatment of hyperactive children. It has also been considered to be effective in the overall behavioral treatment/management of children with petit mal seizure disorders, mental retardation, learning disabilities and autism (Feingold, 1976a). For example, Feingold (1976b) states that

> "In retardation the clinical response may be dramatic, as evidenced by improved behavior, better coordination of both fine and gross muscles, and improved learning ability. All of these gains induce a marked transformation in the patient,

> whose expression becomes more alert and bright, his social adjustment improves, permitting him to function as a self-sufficient person who does not require one-to-one attention or instruction." (p.558)

Such promising statements, unfortunately, have not been derived from systematic data collection or experimental studies, thus making it impossible to critically evaluate the claimed efficacy of the elimination diet in these diverse diagnostic categories.

Although the results of the Phase I and Phase II experiments are in large part negative with respect to supporting the Feingold hypothesis, it is not possible from our data to categorically dismiss the possibility that a small subset of children (especially those of pre-school age) may demonstrate hyperkinetic symptoms following the ingestion of food additives (synthetic food flavors and colors). In contrast to these modest and guarded conclusions from controlled investigations, Feingold has stated that approximately 50% of hyperactive children treated with the K-P diet program show a successful response. A general description of an expected response to the K-P diet program is as follows: "a complete change in the child may be observed within a week or two and sometimes within a few days. The child becomes quiet, docile, affectionate and cooperative. The sleep pattern improves. Improved scholastic performance usually follows very rapidly." (Feingold, 1976a, p.9). Anecdotal case reports of dramatic and impressive improvement in the child's behavior subsequent to being maintained on the K-P diet have been presented in detail (Beall, 1973; Feingold, 1975). Based upon these clinical and personal reports, Feingold (1976b) believes that it is imperative to implement the use of logo to assist the consumer in identifying products not containing artificial food colors and flavors, plus the establishment of "controlled" school lunch programs. Such action has been recommended even though

Feingold (1976a)acknowledges that:

> "It is true that the mechanisms involved are not known, nor have the specific compounds been identified. But such basic data will require many years of well controlled research. It is not necessary to await the availability of basic data. It has been demonstrated that these children respond to dietary intervention. That is the immediate and urgent need to halt and reverse the persistent rise in scholastic failures, vandalism, delinquency and crime." (p. 12).

The Feingold diet clearly offers an appealing, relatively simple treatment for a very large number of children who have rightly or wrongly been labeled hyperactive. Parents are typically attracted to the diet treatment program because of dissatisfaction with other therapies that have been tried. They are frequently seeking alternatives to medication and other treatment modalities because of deeply felt negative attitudes and convictions regarding synthetic substances, and positive attitudes (which are strongly supported by the current social-environmental "Zeitgeist") towards natural food products. The diet may help to reduce the parents' feelings of guilt or other negative emotions involving their hyperactive child because an "outside" causative agent has now been identified which helps to minimize any threatened experience of blame on the part of the parents. The numerous Feingold associations which have been established across the country may also contribute to a positive expectancy effect and to a collective parental identity and conviction of making common cause against exploitation by industry "others".

These kinds of cautious, even pedestrian, alternative interpretations of the positive anecdotal clinical reports have been preempted by the ready admission that placebo and expectancy effects may indeed be operative but that what is important is the fact of improvement, regardless of the mechanisms involved.

Nonetheless, it must be emphasized that when data are collected by means of rigorous experimental designs which minimize potential sources of subjective bias and positive behavioral outcome expectancy, diet-related behavioral changes are much less spectacular than are the impressive clinical case studies and fervent parental testimonials which have been so widely disseminated.

By its very nature, experimental research cannot offer absolute answers to the issue being investigated here, although it is now evident that numerous attempts by scientists in the United States (Conners, et al., 1976; Conners and Goyette, 1977; Harley, et al., 1978; Spring, et al., 1978), Canada (Williams, et al., 1978) and Australia (Levy, et al., 1978) to experimentally document the spectacular claims that have been associated with dietary intervention have been in large part unsuccessful. While little research support has been found for these clinical reports with respect to school age children, some data (including our own Phase I study) do suggest that there may be a small subgroup of younger children who display adverse behavioral reactions to particular synthetic food substances, and hyperactive children in this age group clearly deserve further study. Firm scientific conclusions regarding this entire investigative area have not yet been reached and may not be for a considerable period of time. Nonetheless, the results of controlled experimental investigations of the Feingold hypothesis presently available appear to be at sufficient variance with the positive clinical-anecdotal reports to suggest that the unqualified advocacy of sweeping diet-related treatment recommendations is distinctly premature at this time.

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